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House of Representatives

The House met at 10 a.m.

The Reverend Richard Estrada, Executive Director, Jovenes, Inc., Los Angeles, California, offered the following prayer:

Let us begin this morning by acknowledging the presence of God the Almighty. Lord, we praise You for having given us this good Earth and having called us to take care of her resources. Lord, you have blessed us with opportunities and freedom for people of all backgrounds.

Lord, inspire our Nation's leaders to seek justice, defend liberty, and unite diverse cultures and languages. Lord, bless our Nation's Representatives here today. Fill them with Your wisdom to make laws that will provide for all.

Lord, You made us in Your own wonderful image. Look with compassion on families. Remove the arrogance and hatred that infects our hearts. Break down walls that separate us. Unite us in bonds of love. Work through our struggles to accomplish Your purpose. In time, all people will serve You in harmony.

Lord, God Almighty, we humbly ask You to bless us now and forever. Amen.

THE JOURNAL

The SPEAKER. The Chair has examined the Journal of the last day's proceedings and announces to the House her approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

Mrs. MILLER of Michigan. Madam Speaker, pursuant to clause 1, rule I, I demand a vote on agreeing to the Speaker's approval of the Journal.

The SPEAKER. The question is on the Speaker's approval of the Journal.

The question was taken; and the Speaker announced that the ayes appeared to have it.

Mrs. MILLER of Michigan. Madam Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER. Pursuant to clause 8, rule XX, further proceedings on this question will be postponed.

The point of no quorum is considered withdrawn.

PLEDGE OF ALLEGIANCE

The SPEAKER. Will the gentlewoman from California (Ms. SOLIS) come forward and lead the House in the Pledge of Allegiance.

Ms. SOLIS led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

MESSAGE FROM THE SENATE

A message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 1124. An act to extend the District of Columbia College Access Act of 1999.

The message also announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S.558. An act to provide parity between health insurance coverage of mental health benefits and benefits for medical and surgical services.

WELCOMING THE REVEREND RICHARD ESTRADA

The SPEAKER. Without objection, the gentlewoman from California (Ms. SOLIS) is recognized for 1 minute.

There was no objection.

Ms. SOLIS. Thank you, Madam Speaker, and good morning to all.

It's a privilege and honor today to welcome a dear friend of mine, Father Richard Estrada, who traveled from Los Angeles to be here to provide the House with its opening prayer. I am delighted to present Father Estrada to my colleagues, and I want to thank him for taking the time to be here.

As we celebrate Hispanic Heritage Month, it is fitting to have Father Estrada serve as guest chaplain. Father Estrada has dedicated his entire life to serving those less fortunate than us, particularly the homeless and at-risk youth.

He is the founder and executive director of Jovenes, Inc., a nonprofit organization which serves the homeless and at-risk immigrant youth and other disadvantaged individuals from the East Los Angeles area. He is the associate pastor at Our Lady Queen of Angels Catholic Church, La Placita, the oldest church probably in the country.

Father Estrada received a bachelor of arts degree from the University of San Francisco and studied theology and pastoral counseling at the Graduate School of Theology in Berkeley, California, the Mexican American Cultural Center in San Antonio, Texas, and the Fred C. Neiles School in Whittier, California.

In addition to his advocacy on behalf of the homeless and young people, Father Estrada is a champion for the humane treatment of all immigrants and their families. In fact, I recall him asking me to go with him across the border to place bottles of water for those immigrants that were dying in the fields and in the desert.

I ask my colleagues to welcome Father Richard to the House today. We have before us a great man of honor and compassion.

ANNOUNCEMENT BY THE SPEAKER

The SPEAKER. The Chair will entertain up to 15 1-minute speeches on each side.

PRIVATIZATION OF IRAQI OIL—SPOILS OF WAR TO BUSH ALLY?

(Mr. KUCINICH asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. KUCINICH. The recent oil deal between the U.S.-based Hunt Oil Company and the Kurdistan Regional Government raises questions since Hunt Oil, a privately held oil company based in Texas and its founder, Ray Hunt, have close ties to Vice-President CHENEY and are large donors to President Bush. The deal also appears to undercut the goal of oil revenue sharing but is predictably consistent with the administration's attempt to privatize Iraqi oil assets. Both Hunt Oil Company and Kurdistan are strong allies with the Bush administration.

As I have said for 5 years, this war is about oil. The Bush administration desires private control of Iraqi oil, but we have no right to force Iraq to give up control of their oil. We have no right to set preconditions for Iraq which lead Iraq to giving up control of their oil. The Constitution of Iraq designates that the oil of Iraq is the property of all Iraqi people.

I am calling for a congressional investigation to determine the role the administration may have played in the Hunt-Kurdistan deal, the effect the deal could have on the oil revenue sharing plan and the attempt by the administration to privatize Iraqi oil.

EARMARKING THE SWAMP

(Mr. FLAKE asked and was given permission to address the House for 1 minute.)

Mr. FLAKE. Mr. Speaker, after we Republicans lost the majority in last year's elections, the new majority promised that they would ''drain the swamp.'' The new majority seemed to recognize that the political cost of earmarks far outweighed the benefits, and modest reforms were instituted to make the process more transparent.

However, it soon became clear that the earmark reform rhetoric was not matched by reality. The old majority seems just as mired in the mud as the old.

Still, it was with some excitement that I recently discovered in the House-passed Interior appropriations bill a $750,000 earmark for the Great Swamp National Wildlife Preserve in New Jersey. Predictably, this earmark was not to drain the swamp, but to preserve it.

This begs the question: If we can't stop passing earmarks to preserve swamps, how will we ever drain the earmark swamp?

Mr. Speaker, our constituents and this institution deserve far better. Let's follow up on our promises for earmark reform with actual reform.

THE NEED TO INSURE MORE OF AMERICA'S CHILDREN

(Mr. BUTTERFIELD asked and was given permission to address the House for 1 minute.)

Mr. BUTTERFIELD. Mr. Speaker, the news about health care in our Nation continues to get more discouraging, especially when it comes to health insurance for children. New Census data shows that the number of children without health insurance in the United States has grown over the last year by 700,000, to nearly 8.7 million children. This means that now one in nine American kids do not have health insurance.

To try and reverse these unacceptable trends, the Democratic Congress voted last month to reauthorize the Children's Health Insurance Program. Our legislation will provide an additional 5 million low-income children with the health insurance they need to live healthier lives. These kids are already eligible but not enrolled.

Mr. Speaker, President Bush has threatened to veto this legislation, despite bipartisan support it received in Congress and from our Governors. In the face of these discouraging new Census numbers, it is time for the President to end his veto threat and pledge his support for this legislation that will provide 11 million children with the health care coverage they need and deserve.

OH NO! ANOTHER TAX INCREASE

(Mr. POE asked and was given permission to address the House for 1 minute.)

Mr. POE. Mr. Speaker, as air travel increases, revenue to airports, of course, increases as well. Much of that money is from hidden taxes passengers pay. But now this increased revenue isn't enough for some. They want to tax flyers even more to fly.

Right now, if a citizen buys a typical round trip ticket, the fare is about $230. But additional taxes raise the fare another $45. So the passenger is now really paying $275.

Airports now want to collect more Federal taxes from each passenger by increasing the passenger facility charge, another word for tax, to $7 per passenger per segment. What that means is a family of four that flies from Odessa, Texas, to Washington, D.C., with a stopover in Dallas, is going to pay another $112 in more taxes.

Airports already get plenty of money. They sell bonds; they get millions in Federal, City and State taxes; they charge airlines for gates and the right to land; they get taxes off rental cars; and they lease airport space to businesses.

Airports should make do with the abundance of revenue they already get from the taxpayers. Don't raise taxes any more on passengers.

And that's just the way it is.

□ 1015

HUNT OIL

(Mr. WELCH of Vermont asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. WELCH of Vermont. Mr. Speaker, while President Bush is asking Congress and the American people to give his failed policy in Iraq more time, even some of the President's closest allies don't believe the strategy will work.

Last week, it was reported that Hunt Oil Company of Dallas, Texas had signed an oil exploration and production deal with the Kurdish Regional Government. That Hunt Oil Company is owned by Ray Hunt, major campaign supporter of President Bush and a member of the President's Foreign Intelligence Advisory Board. His decision to bypass the Iraqi Government in Baghdad and negotiate directly with the Kurds shows his lack of confidence that Iraq will develop a functioning government in the near future, and it undermined important efforts for the Iraqi oil sharing law, which collapsed last week.

While President Bush is asking our Nation to sacrifice more of our brightest young soldiers and to spend hundreds of billions more in taxpayer dollars in pursuit of his Iraq strategy, one of the President's closest allies and advisers is betting that his strategies will continue to fail and, in fact, is looking to profit from it.

VETERANS APPROPRIATIONS BILL

(Mr. WALBERG asked and was given permission to address the House for 1 minute.)

Mr. WALBERG. Mr. Speaker, as I travel throughout my south-central Michigan district, I have learned over the past few months in town hall meetings, small group meetings, or coffees, that virtually all Americans believe we owe a great debt of gratitude to those who have worn the uniform in service to our country.

Unfortunately, Democrat leadership in both Chambers appears willing to make the veterans appropriations bill, which funds our Nation's veterans health care, become part of political gamesmanship in Washington.

It appears Democrats may withhold sending this bipartisan veterans funding bill to the President in an effort to ensure greater spending levels for their pet projects. There is a chance Democrats will hold off on final passage of this legislation so they can include it in a massive budget-busting spending bill at the end of the year.

Let me be very clear. The funding of veterans should not be a political issue. Congress should swiftly pass this important legislation, and Republicans and Democrats should jointly celebrate when it becomes law.

BUSH REFUSES TO BUDGE FROM THE STATUS QUO IN IRAQ

(Mr. BRALEY of Iowa asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. BRALEY of Iowa. Mr. Speaker, last week President Bush told the American people that the status quo would continue in Iraq for 10 months. Last year, the American people demanded a change of course in Iraq. They wanted us to begin the process of bringing our troops home. The President's response: a troop escalation plan that sent an additional 30,000 troops to Iraq.

At the time, he said that if the Iraqi Government did not meet certain economic and political benchmarks, they would lose the support of our Nation. After months of delay, September became the moment of truth; and despite the fact that the nonpartisan GAO report found that the Iraqi Government had failed to fully meet 15 of the 18 benchmarks, the President said the troop escalation plan is going to continue until next summer.

Mr. Speaker, it is now clear that the President's only plan for Iraq is to stay the course until he can hand off the war to his successor.

The time for stalling is over. Staying the course is no longer acceptable. It is time for Republicans to join us in charting a new course.

OUR DOMESTIC AUTO INDUSTRY

(Mrs. MILLER of Michigan asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Mrs. MILLER of Michigan. Mr. Speaker, there has been a great deal of talk over the years that the Big 3 domestic auto companies have been too generous in providing pay and benefits to their workers which has made them less competitive.

I think it is wrong that these companies that helped, literally helped, create the American middle class have been attacked in such a way, but detractors of our domestic auto industry fail to understand that blatant cheating by foreign competitors and foreign governments on such matters as currency manipulation and piracy of intellectual property distort the marketplace and give foreign companies a competitive advantage. Detractors now want to expand the attack on our domestic auto industry by imposing draconian fuel economy standards that will benefit foreign companies and cost American jobs.

Enough is enough. The American auto companies and the UAW are poised to revolutionize the way health care and other benefits are delivered to autoworkers, retirees, and their family members; and, at the same time, the companies and their incredible scientists are working on new technologies for the vehicles of the future that will significantly reduce our dependence on foreign oil. Now is not the time for increased government regulation that will simply kill American jobs.

DEMOCRATIC CONGRESS SENDS COLLEGE COST REDUCTION ACT TO THE PRESIDENT'S DESK

(Mr. SIRES asked and was given permission to address the House for 1 minute.)

Mr. SIRES. Mr. Speaker, elections do make a difference. Last November, Democrats promised that if the American people entrusted us with the control of Congress, one of our top six priorities would be putting college in reach for more Americans.

This week, the Democratic Congress delivers on that promise, sending the College Cost Reduction and Access Act to the President's desk for his signature. The President says he will sign it, which is good news for millions of students and families who are trying to fulfill the American Dream.

The landmark legislation is the largest college aid expansion since the GI Bill in 1944. Under the legislation, the maximum Pell Grant scholarship will increase by more than $1,000 over the next 5 years. More than 5.5 million low- and moderate-income students will receive an immediate boost of almost $500 in their Pell Grant scholarships. The legislation also cuts interest rates in half on student loans, which will save the average student $4,400 over the life of the college loan.

Mr. Speaker, the Democratic Congress has delivered on another of our top priorities as we take America in a new direction.

UNNECESSARY DELAY IN PASSING VETERANS APPROPRIATIONS

(Mr. PEARCE asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. PEARCE. Mr. Speaker, I rise today to call attention to the unnecessary delay in passing this year's veterans appropriations.

This year's veterans appropriations passed with an overwhelming majority in both Houses, 409–2 in this body and 92–1 in the Senate. This kind of bipartisanship makes it clear to all that Congress takes its obligation to our Nation's veterans very seriously.

I sincerely believe America's veterans want to see a final version of veterans funding quickly passed so they may receive the desperately needed funding. However, I feel this will not be the case. Last week, one Democratic aide, asked about this year's veterans appropriations, was quoted in Roll Call saying, ''These bills constitute the little bit of leverage we have.''

Mr. Speaker, the sacrifices that our young men and women are making in Iraq and Afghanistan are not leverage. The tragedies that occurred at Walter Reed are not leverage. Veterans health care is not political leverage. We must recognize that veterans funding is critical and should not be used for partisan politics.

I urge my colleagues to rise above the partisan bickering and pass this. Our veterans are demanding: Do not betray us.

COLLEGE COST REDUCTION & ACCESS ACT: DEMOCRATS ACT ON MAKING COLLEGE MORE AFFORDABLE

(Mr. HINOJOSA asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. HINOJOSA. Mr. Speaker, according to the U.S. Department of Education, an estimated 200,000 academically qualified students are not able to go to college every year because they can't afford the cost.

This is a dangerous trend for our Nation, but it is not surprising. Under the Bush administration, prices at public colleges have increased by 40 percent after inflation. And under Republican rule, Pell Grants remained stagnant for 4 years in a row.

When our Democratic majority was elected, we pledged to address this growing crisis, and this week are fulfilling that pledge by sending the College Cost Reduction and Access Act to the President's desk. This important legislation provides the single largest increase in college aid since the GI Bill, increases the maximum Pell Grant over the next 5 years, and cuts interest rates in half on need-based student loans.

Mr. Speaker, this legislation will help millions of students across our Nation afford a college education without saddling themselves with thousands of dollars in debt, and it is the latest example of what the Democratic Congress is doing.

SCHIP

(Mrs. BLACKBURN asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Mrs. BLACKBURN. Mr. Speaker, I rise today as a strong supporter of the State Children's Health Insurance Program, SCHIP, and I support a responsible reauthorization of this very successful program.

Everybody knows it is going to expire on September 30, unless Congress passes reauthorizing legislation by this date. However, the Democrat leadership in the House and the Senate have been unsuccessful in completing the package.

I am proud today to stand as an original cosponsor of legislation that would reauthorize SCHIP for a period of 18 months. By reauthorizing the program for an additional 18 months, we are taking the politics out of SCHIP policy and protecting the children who

are in this program and who deserve the care. It is an extension of the program that we need; and, if it is not enacted, at least 12 States are going to find themselves without SCHIP funds.

There is a very simple solution to the SCHIP problem: Support the Barton-Deal SCHIP legislation.

NEW BUSH ADMINISTRATION RESTRICTIONS TO THE CHILDREN'S HEALTH INSURANCE PROGRAM

(Mr. ARCURI asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. ARCURI. Mr. Speaker, last month the Bush administration dealt yet another blow to uninsured Americans, this time focused on millions of uninsured children in our Nation.

New guidelines set forth by the administration require that children must go without health insurance for at least 1 year before States will be allowed to provide them with coverage under the Children's Health Insurance Program. The administration also requires States to enroll at least 95 percent of the children below 200 percent of the Federal poverty level before they can provide health coverage to other low-income children, a standard that no State in the country can currently meet. The Bush administration is limiting the very flexibility that has made the CHIP program successful.

Mr. Speaker, it is unconscionable for the President to require low-income children to spend a year of their lives without health insurance, especially when we have a program in place that can provide them with the coverage they need today. It is time for the President to stop playing political games with the children's health care and to vow to work with us to strengthen, not weaken, the CHIP program.

CONGRATULATING MISS ANN MIRON

(Mrs. BACHMANN asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Mrs. BACHMANN. Mr. Speaker, too often we heard about the negatives of America's teenagers, but today I rise to congratulate the work of a wonderful young accomplished woman from my district, the Sixth District in Minnesota. Her name, Mr. Speaker, is Ann Miron of Hugo, Minnesota. She is a very accomplished young woman, representing the next generation of American dairy farmers, being an American dairy farmer herself at age 19.

She descends from a long line of Minnesota dairy farmers, living on a country dairy farm, and she was just recently crowned Princess Kay of the Milky Way. In Minnesota, this is a pretty big deal at the county fair. She was crowned Princess Kay, and Ann Miron will begin a year of speaking and promoting Minnesota area dairy farms.

I am privileged to represent the area with the largest number of dairy farms in the State of Minnesota, and even more privileged to have married a dairy farmer myself.

Ann, I join your great parents, Mayor Fran Miron of Hugo, Minnesota, Mary Ann Miron, and the people of Minnesota to wish you a wonderful year promoting dairy farming in the State of Minnesota.

REAL PROGRESS IS NOT BEING MADE IN IRAQ—IT IS TIME FOR A CHANGE OF COURSE

(Mr. PALLONE asked and was given permission to address the House for 1 minute.)

Mr. PALLONE. Mr. Speaker, President Bush says progress is being made in Iraq, but many of the examples he pointed to in the nationally televised speech last week were overestimated or overly optimistic. Let me just cite a couple examples.

First, President Bush said, ''Iraq's national leaders are getting some things done, such as sharing oil revenues with the provinces.'' But according to the Washington Post, the President's statement ignored the fact that U.S. officials have been frustrated that none of these actions have become law and that a possible compromise has collapsed.

The President also thanked ''the 36 nations who have troops on the ground in Iraq.'' But if he had checked with his own State Department, he would have realized that only 25 countries are still involved in the war, supplying only 11,600 troops. Now, that is less than 7 percent of the size of the U.S. forces still on the ground.

Mr. Speaker, this is nothing new. The President has been painting rosy scenarios for the situation in Iraq from the very beginning. Time and time again they have been proven wrong. The status quo simply can't continue. It is time to change course.

REENACT FISA

(Mr. DANIEL E. LUNGREN of California asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. DANIEL E. LUNGREN of California. Mr. Speaker, yesterday in the House Judiciary Committee we heard from Admiral McConnell, who is the Director of National Intelligence, over the need for us to reenact that bill which we passed just 1½ months ago which reformed FISA, which of course is the Foreign Intelligence Surveillance Act.

Mr. Speaker, probably in the 3 years that I have been here, in my second tour of duty as a Member of Congress, no more important bill did I vote on than voting the passage of a reform of FISA.

The admiral indicated that two-thirds of our foreign terrorist targets were blinded from our review as a result of a FISA court decision under the old FISA. That is why we needed to pass the reform. We put a 6-month leash on it, that is, it will go out of existence in 6 months.

There is no more important thing for this body to do than to pass a reform of FISA that makes permanent the changes that we adopted just 1½ months ago. Our Nation depends on it. Our children and our grandchildren's future depends on it. Let's make sure we act responsibly.

□ 1030

MY FIRST VISIT TO ISRAEL

(Mr. MCHENRY asked and was given permission to address the House for 1 minute.)

Mr. MCHENRY. Mr. Speaker, traveling to the Holy Land in August, I saw firsthand the challenges facing our ally and friend, Israel. From Syria, the terrorist state in the north, to Lebanon and the chaos existing there further to the north, to the enemies that surround the state, I saw the challenges traveling down the Galilee to the Jordan, down to the Dead Sea and going to the capital, Jerusalem.

While it was my great privilege to walk on that sacred holy ground, I also realized the eye-opening national security issues that they face as a nation. Israel is our greatest ally in the war against Islamic extremists, and it is our function to support them in Israel. It is our imperative to support them. That's why our 10-year security agreement that we recently signed between the United States and Israel is so necessary for the ongoing security, not just of Israel, but of the United States. Israel's enemies are our enemies. We share a common cause, and it is necessary that we stand strong for Israel because it makes us that much stronger.

I encourage the American people to support our greatest ally in the Middle East, Israel.

PROVIDING FOR CONSIDERATION OF H.R. 2761, TERRORISM RISK INSURANCE REVISION AND EXTENSION ACT OF 2007

Mr. ARCURI. Mr. Speaker, by direction of the Committee on Rules, I call up House Resolution 660 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

H. RES. 660

Resolved, That at any time after the adoption of this resolution the Speaker may, pursuant to clause 2(b) of rule XVIII, declare the House resolved into the Committee of the Whole House on the state of the Union for consideration of the bill (H.R. 2761) to extend the Terrorism Insurance Program of the Department of the Treasury, and for other purposes. The first reading of the bill shall be dispensed with. All points of order against consideration of the bill are waived except those arising under clause 9 or 10 of rule XXI. General debate shall be confined to the bill

and shall not exceed one hour equally divided and controlled by the chairman and ranking minority member of the Committee on Financial Services. After general debate the bill shall be considered for amendment under the five-minute rule. The amendment in the nature of a substitute recommended by the Committee on Financial Services now printed in the bill, modified by the amendment printed in part A of the report of the Committee on Rules accompanying this resolution, shall be considered as adopted in the House and in the Committee of the Whole. The bill, as amended, shall be considered as the original bill for the purpose of further amendment under the five-minute rule and shall be considered as read. All points of order against provisions in the bill, as amended, are waived. Notwithstanding clause 11 of rule XVIII, no further amendment to the bill, as amended, shall be in order except those printed in part B of the report of the Committee on Rules. Each further amendment may be offered only in the order printed in the report, may be offered only by a Member designated in the report, shall be considered as read, shall be debatable for the time specified in the report equally divided and controlled by the proponent and an opponent, shall not be subject to amendment, and shall not be subject to a demand for division of the question in the House or in the Committee of the Whole. All points of order against such further amendments are waived except those arising under clause 9 or 10 of rule XXI. At the conclusion of consideration of the bill for amendment the Committee shall rise and report the bill, as amended, to the House with such further amendments as may have been adopted. The previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions.

SEC. 2. During consideration in the House of H.R. 2761 pursuant to this resolution, notwithstanding the operation of the previous question, the Chair may postpone further consideration of the bill to a time designated by the Speaker.

The SPEAKER pro tempore (Mr. PASTOR). The gentleman from New York is recognized for 1 hour.

Mr. ARCURI. Mr. Speaker, for purposes of debate only, I yield the customary 30 minutes to the gentleman from Texas (Mr. SESSIONS). All time yielded during consideration of this rule is for debate only. I yield myself such time as I may consume. I also ask unanimous consent that all Members be given 5 legislative days in which to revise and extend their remarks on House Resolution 660.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New York?

There was no objection.

Mr. ARCURI. Mr. Speaker, House Resolution 660 provides for consideration of H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act of 2007 under a structured rule. The rule provides 1 hour of general debate to be controlled by the Committee on Financial Services. The rule also makes in order the substitute reported by the Committee on Financial Services, modified by the amendment in part A of the Rules Committee report, as an original bill for the purpose of amendment. The self-executing amendment in part A would ensure that the bill complies with the new PAYGO requirements. It would require the enactment of a joint resolution to permit Federal compensation under the Terrorism Risk Insurance Act of 2002. The joint resolution, approving a certification by the Secretary of Treasury, in concurrence with the Secretaries of State, Homeland Security and the Attorney General, that there has been an act of terrorism, would be considered by Congress under fast-track procedures.

The rule makes in order two amendments printed in the Rules Committee report, each debatable for 10 minutes.

Mr. Speaker, the Terrorism Insurance Program was originally enacted as a short-term backstop for an insurance industry that was very hard hit by the terrorist attacks that occurred on September 11, 2001. In the years since, we have seen that the private insurance market is unable to cover the risk of both domestic and foreign acts of terrorism without assistance.

The original legislation, the Terrorism Risk Insurance Act, referred to as TRIA, was set to expire at the end of 2005. The Terrorism Risk Insurance Extension Act of 2005 extended the government backstop for two more years, through the end of this year, but left the long-term questions surrounding the program unanswered. Those unanswered questions include: whether the government-run terrorism insurance program is really necessary; how to manage the possibility of a nuclear, biological, chemical or radiological attack, and how best to allocate the risk of terrorist attack between the government and private insurers. The rule provides for consideration of a bill that answers those questions.

Experience has shown that there is a true need for government involvement in terrorism insurance. The exposure for private companies is just too great. In the wake of September 11, 2001, many companies opted to exclude terrorism risk from private insurance policies, leaving no coverage in the event of another attack. TRIA requires primary insurers to make terrorism insurance available to commercial clients that wish to purchase it while at the same time helping those insurers manage their exposure to risk of loss.

The legislation this rule provides for consideration will extend TRIA for 15 years and make necessary revisions aimed at furthering the development of a private market of terrorism risk insurance. Such a long-term extension is vital because it provides certainty and stability to the insurance and real estate markets.

People may think that TRIA is only an issue for businesses in New York City, but that is clearly not the case. In the upstate New York district which I represent, small insurance companies like Utica First, Preferred Mutual and Utica National felt the dramatic impact that 9/11 had on the private market. In the year that followed the September 11 attacks, Utica First saw the volume of policies they were writing in the New York City area increase 27 percent as other companies ceased offering coverage. In order to do so, they risked both their existing surplus and their industry ratings and also incurred greater expense because their own reinsurance required that they purchase a separate terrorism cover. Small companies like this, that continued to offer coverage, are to be commended for taking on greater risk exposure in order to provide the necessary coverage and allow businesses to continue in business and people to continue to work to support their families.

The legislation would also require insurers to offer coverage for nuclear, biological, chemical and radiological terrorist acts. Small insurers, like those in my district, are especially concerned about the effect of adding the nuclear, biological, chemical and radiological requirements to TRIA, but the risk of such an attack is real, and not having any system in place would enhance the devastating effect such a horrific attack would have if it were to happen again in our country.

This bill strikes a good balance because it not only phases in the nuclear, biological, chemical and radiological coverage beginning in 2009, but also provides small insurers, those whose direct earned premium is less than $50 million, the ability to apply for an exemption of up to 2 years with the possibility of further extending that exemption.

This legislation would also make several other critical changes to the terrorism risk insurance program. It would change the definition of terrorism under TRIA to include domestic terrorism, and reset the program trigger level at $50 million. It would expand the program to provide for group life insurance coverage, would decrease deductibles for terrorist attacks costing over $1 billion, and reduce the trigger level in the event of such an attack. Finally, it would require studies on the development of a private insurance market for terrorism risk insurance.

Mr. Speaker, this legislation is a critical step in protecting our national and economic security in the fight against terrorism.

Mr. Speaker, I reserve the balance of my time.

Mr. SESSIONS. Mr. Speaker, I rise in strong opposition to this modified closed rule that shuts down debate in the House to every Member of this body, except the chairman of the Financial Services Committee, who has already had ample time and opportunity to modify this legislation, and to one token Republican amendment.

Two nights ago, in the Democrat Rules Committee, which over the last year has truly solidified its reputation as the graveyard of good ideas in the House of Representatives, we had a wide-ranging discussion from Members on both sides of the aisle about their

proposals to improve this legislation. We adjourned this meeting without reporting out a rule so that alternatives to subverting the Rules Committee jurisdiction, while sticking to the Democrat pay-for rule, could be studied. Unfortunately, when the opportunity came for the majority to make good on its campaign promises to run the most honest, ethical and transparent House in history by providing an open and transparent legislative process, Members of this House were, once again, silenced by the heavy-handed Democrat leadership.

While I am no longer surprised by the Democrat leadership's decision to allow politics to prevail over good government, I'm still disappointed, because as the sponsor of legislation to extend the TRIA program in the 108th Congress, I fundamentally believe that it has helped the private sector to stabilize our Nation's economy by providing a functioning marketplace for policyholders to acquire terrorism insurance and for insurers to provide it to them.

In fact, many of the positive aspects of this bill mimic policy proposals included in my legislation, and in legislation introduced last Congress by my good friend from Louisiana, RICHARD BAKER. Like these Republican bills, today's legislation would extend the current program, providing both policyholders and insurers with the certainty needed for long-term projects and our domestic economic health to move forward.

And, like prior Republican legislation, today's bill would eliminate the false distinction between foreign and domestic acts of terror. As we have learned from the London bombings and from the recent foiled terrorist plots in Germany and in New Jersey, no country is insulated from home-grown terrorism, which can be just as destructive and as costly as terrorists from abroad.

Other aspects of this legislation, such as the inclusion of nuclear, biological, chemical, or radiological coverage, mimic past Republican proposals without including market-based modifications that our proposals also contained in order to make this coverage both taxpayer friendly and cost efficient.

Unfortunately, there's one proposal in today's legislation that is unprecedented and that I simply cannot support. Written in the Rules Committee, without any consideration or debate in the Financial Services Committee, and then self-executed by the rule so that it receives no up-or-down vote, this rule contains language that skirts recent Democrat promises to abide by their own self-imposed PAYGO rules by shifting the responsibility of funding TRIA onto future Congresses.

□ 1045

By including this mandate on future Congresses, which the Supreme Court has roundly rejected as unconstitutional, the market stabilization benefits of TRIA completely evaporate.

Rather than helping to provide insurers and policyholders with the certainty that they need to manage their exposure to the financial costs of terrorism, this bill simply kicks the responsibility down the road and by and large says ''we will let somebody else worry about that.''

Rather than clearly signaling to the private sector what the Federal Government will spend in the event of another attack on the United States and what their own costs and responsibilities would be, this hastily drafted language, shoved in in the middle of the night, reintroduces political risk into this financial transaction by leaving these hard decisions up to the whims of a future Congress.

Mr. Speaker, I think this Congress should do better and they can do better than this. Instead of closed rules and artful dodges of the PAYGO rule, I think that Members and their constituents deserve the openness promised by Democrat leadership. Instead of procedural trickery and inserting language of a mysterious origin into this rule without any minority input or open debate, I think that Members and their constituents deserve transparency, which was promised by the Democrat leadership. And, most of all, instead of leaving the hard decisions and potential costs of this program to future Congresses, I believe that Members and their constituents deserve a bill that deals honestly with one of the most serious problems facing the American economy.

Unfortunately, this bill provides none of these things and is a far less responsible approach to dealing with the real-world economic problems posed by terrorism to our country, more than past Republican proposals. In fact, about the best thing that can be said about this bill and the process under which it is being considered today is the fact that perhaps it will spur the Senate to provide the American people with a more serious proposal in dealing with TRIA so that all of the flaws of this legislation can be worked out in conference.

I oppose this rule and encourage all of my colleagues on both sides of the aisle to do the same.

Mr. Speaker, I reserve the balance of my time.

Mr. ARCURI. Mr. Speaker, I yield 6 minutes to the gentleman from Massachusetts (Mr. FRANK).

Mr. FRANK of Massachusetts. Mr. Speaker, there are several aspects of this. One is, of course, whether or not we should go forward with a renewal of terrorism risk insurance.

There are, in our midst, people who believe in the free market so firmly that they believe in it the way other people believe in unicorns. They believe in it even when it does not exist. There are people who oppose terrorism risk insurance from the outset and continue to because they say it should be up to the market. No one involved in the market thinks that makes sense. Indeed, we received a letter from the head of Goldman Sachs in 2005 saying there is no evidence that this can become a market item. His name was Henry Paulson, and he quite clearly said at the time the market wouldn't do it. We then proceeded with a bill that took that into account.

By the way, if the market could do it, it shouldn't because here is what the market would do, and we are talking about the insurance market: If you left this to the market or if you try to phase this out so the market would take it over, the principle of insurance says it should be more expensive to do business in those parts of the country which are likeliest to be hit by terrorists than not because that's the insurance principle. If there is a higher risk, you charge people more. We should not allow murderous fanatics who seek to damage this country to dictate what the cost of doing business is in different regions. That's not a market decision; that's a national security decision. I don't want it to be more expensive because of the murderers who would try to undermine this country to do business here or there.

It is also the case that one of the principles of insurance is that you give it and you give incentives to the insured to reduce the risk and you price in a way that gives those incentives. People can't avoid the risk. There is nothing you can do to stop the terrorists as private citizens from attacking you.

So we were going ahead with the bill. Now, we had a set of markups in subcommittee and committee in which there were some disagreements but some agreements. A number of amendments offered by Republican Members were adopted and the bill had a very large vote coming out of committee.

We then ran into a surprising obstacle. The Congressional Budget Office issued what seems to me an intellectually quite weak opinion. They said this is going to cost $10 billion over the next 5 years. Now, a $10 billion terrorism attack is not within our contemplation. I could see their saying it is not going to cost anything for this period or that it is going to cost hundreds of billions. Apparently they calculated the probability of a terrorist attack and imputed that cost. There will, in fact, be no costs until there is an attack.

My own view, frankly, was that this would have justified an emergency waiver under PAYGO. If being attacked by terrorists, if September 11, 2001, was not an emergency, then I don't understand what the word means.

We have been forced now to try to deal with this in other ways, and I understand that. It has been forced on us by CBO. The notion that we can say something now and leave it to future Congresses, the gentleman from Texas said it was unconstitutional. I am aware of no Supreme Court decision that would invalidate what we have

proposed here. And it couldn't be binding. Nothing is binding of one on a future one. I think that would be a very high degree of probability.

So we do have this approach which came up suddenly. It came up suddenly. It wasn't debated in our committee because the issue of the CBO estimate hadn't come before us in the committee. So we now have Members on the other side complaining that the rule was too restrictive.

Mr. Speaker, when I hear Members of the Republican Party who ran this House in the most blatantly undemocrat fashion for so many years now complain about a lack of democracy, I feel like I am in a motion picture theater and I'm watching an Ingmar Bergman dark movie which features the Three Stooges. The incongruity of these masters of authoritarian legislative procedure now complaining because there isn't enough democracy is one of the great conversions of all time. And I would have to say to my born-again believers in an open process that in this case at the committee level, we had a hearing, we had a subcommittee markup and a committee markup, and we dealt very much with those issues.

My own preference would have been to allow a few more amendments, but the fundamental issues have been debated, and the key issue is, unfortunately, the one that has troubled them, is how do you deal with the CBO. Now, either you do a waiver of PAYGO or you make cuts now of $10 billion in programs on the possibility of there being a terrorist attack. It seems to me that is a great favor to terrorists. Let them cut programs now by just threatening to blow us up. Or you try to come up with some set of procedures that say we really intend to do this but we can't make it absolutely binding.

I do not think the set of procedures we have here will be the final say. It was a difficult situation that we found with that, I thought, CBO estimate. And the CBO estimate basically says here is what we say but it's probably not going to be this way. And I hope, as we go forward, there will be meetings with industry. And, by the way, industry is not just the insurance industry. It's the commercial building industry. They are the ones who are at risk here. The insurance industry can walk away, but if they walk away, we won't get commercial buildings built, particularly in our big cities, which is why the mayors of the big cities are so concerned and others are concerned about economic development.

So we need further work to see how we can deal with this CBO issue, and I think we have a reasonable first cut. It is one where, it is true, we did not deal with it in our committee. What we dealt with in the committee in great detail with a number of amendments and a lot of compromise were all the other factors. And we now get this new issue. This is a good-faith effort to deal with the new issue but not in a way that is final. So I hope we can go forward.

Mr. SESSIONS. Mr. Speaker, at this time I am going to yield to the gentleman from California, who will help us to understand a little bit more clearly about the uncooked and, I believe, sloppy work that was presented to the Rules Committee such that many, many, many Members on a bipartisan basis questioned the decision that was made, and it will help us to reflect upon an opportunity about how it could be done better.

I yield 5 minutes to the ranking member of the Rules Committee, the gentleman from San Dimas, California, the Honorable DAVID DREIER.

(Mr. DREIER asked and was given permission to revise and extend his remarks.)

Mr. DREIER. Mr. Speaker, a week ago yesterday we marked the sixth anniversary of one of the most tragic days in our Nation's history, that being September 11, 2001. We all, in the wake of that tragedy, the likes of which we had never seen in our Nation's history, came together and united in a bipartisan way to deal with the aftermath of September 11 of 2001. One of the many things that we did was realize that we are a Nation at war, and in light of that, the private insurance industry, and I am a free marketeer, the private insurance industry needed to have some kind of Federal backdrop if another horrendous terrorist attack is thrust upon the American people. So I supported the notion of saying, you know what, when we are a Nation at war, the free market can't just automatically protect those who are victimized by that kind of attack. So I became a supporter of this and I worked on it early on and supported the extension of it. And as I stand here today, I still believe that we are a Nation at war and it is imperative that we do everything possible to ensure that we, the Federal Government, stand up and play the role that we have to in leading the fight.

Well, Mr. Speaker, unfortunately, what we are doing with this rule is undermining something that Mr. ARCURI said in his opening remarks that this bill creates: certainty. Mr. ARCURI said that this bill creates certainty. Mr. Speaker, what we are doing with this self-executed provision in this rule, and my friend Mr. ACKERMAN from New York understands this very well, is we are completely obliterating any kind of certainty.

Now, this was designed as a mandatory program. Mandatory, why? Because if we face the attack, there needs to be certainty that the Federal Government is behind it. Now, I know that many people will say, oh, of course the Congress is going to take action, of course the Congress will do it. You know what, Mr. Speaker? That is not good enough for people who are investors, people who are in an industry that is responsible for dealing with the aftermath of the kind of attack that we saw on September 11.

That is why I believe it is absolutely imperative that we oppose this rule. We need to do everything that we can in a bipartisan way to defeat this rule. Why? Because we have been given this multipage, self-executing provision which undermines the jurisdiction of the Rules Committee. And that is why I am really hard pressed to believe that any member of the House Rules Committee, the traffic cop for this institution, I believe the single most important committee in this institution, how any member could basically cede the authority that we would have on this. And you look at the other committees of jurisdiction that are completely ignored, the Judiciary Committee. The Budget Committee clearly should be involved in this process. We need to have budget process reform. Our committee, our Rules Committee, Mr. Speaker, should be holding hearings on this. We should look at the issue of dynamic scoring. Yes, the hands of the Congressional Budget Office are tied because they have to look at 5- and 10-year projections. What we need to do is we need to bring about the kind of responsible reform that can ensure, that can ensure that we have the kind of certainty that is necessary.

So, Mr. Speaker, I have got to say that I know that there is strong bipartisan concern about this issue. This is not the way to deal with it. I said if given a simple choice in the Rules Committee between a waiver of PAYGO, which is, I believe, a very flawed rule that was put into place at the beginning of this Congress, or this provision, this self-executing provision, sure, I'd prefer that waiver over that. But there has got to be another solution. And the reason is that this new Congress put into the rules this PAYGO provision, very well intentioned but very, very badly flawed, Mr. Speaker. So I think that if we look at what it is we are doing on this in the name of trying to avoid a waiver of PAYGO, this self-executing provision actually waives PAYGO completely.

□ 1100

And so I've got to tell you, this is a horrible rule; it is a horrible process; it is unprecedented. And I hope the Democrats and Republicans alike will join in saying, yes, we need to have a responsible terrorism risk insurance measure passed, but we need to come down with a provision that responsibly budgets that, and this is not it.

Mr. ARCURI. I think the gentleman is right, this may be unprecedented; but the attack on 9/11 was unprecedented as well, and sometimes unprecedented events require unprecedented action, and that's what we are attempting to do today, create a rule to enact legislation like TRIA to create a backstop so that insurance companies can continue to create a stable environment for business to thrive in New York City.

Mr. Speaker, I yield 4 minutes to the gentleman from Pennsylvania (Mr. KANJORSKI).

(Mr. KANJORSKI asked and was given permission to revise and extend his remarks.)

Mr. KANJORSKI. Mr. Speaker, I rise to support this resolution setting forth the terms of debate for considering H.R. 2761 on the House floor.

The adoption of this rule will allow the House to debate this must-pass legislation to extend the Terrorism Risk Insurance Program. We need to move this process forward as quickly as possible.

I know that some participants in today's debate will raise concerns about the structure of the rule concerning the method by which it addresses issues related to the PAYGO rules. I must concede to them that the proposed rule is imperfect in this regard.

Throughout the debate on this legislation, the chairman of the Financial Services Committee, the gentleman from Massachusetts, and I have agreed that the Terrorism Risk Insurance program is very important. It protects America's economy from terrorist attacks. Certainly, the Federal Government has a role in protecting our Nation from terrorist events.

Moreover, this Federal backstop only responds to an emergency situation and only becomes implemented after a terrorist attack. Because TRIA plans ahead for an emergency caused by terrorists, Congress should treat spending under this law as an emergency.

PAYGO is an important rule that keeps Congress fiscally responsible. PAYGO, however, should not apply to all pieces of legislation, especially those bills that plan ahead for national emergencies caused by terrorists. My view is that all legislation should be fiscally responsible to the maximum extent possible.

Accordingly, I have had concerns about costs throughout the development and debate of this legislation. In fact, I voted, in many instances, to control those costs, such as limiting the length of the extension and increasing the private sector's responsibilities after a reset.

TRIA is not an entitlement program. It is a program for protecting the economic security of our Nation. H.R. 2761 is a necessary piece of legislation that will maintain stability in our economy after a terrorist attack on our Nation, rather than waiting for the government to develop an ad hoc plan after an event.

While we cannot predict when or where the terrorists may choose to attack us, we can prudently plan ahead for such a possibility. Like many participants familiar with this debate, I have concerns about the requirement in this rule to have a separate vote of Congress on funding for the program after an attack. With Federal payments conditioned on a congressional vote even under expedited procedures, much of the certainty of the program is taken away. It is my hope, therefore, that we will continue to work on a better solution before this bill comes back to the House floor in a conference report.

That said, Mr. Speaker, we must move the process forward. I, therefore, urge my colleagues to support this rule on H.R. 2761.

Mr. SESSIONS. Mr. Speaker, I would like to congratulate the gentleman for his fine remarks. As a matter of fact, I agree with him, that I do not believe that it is proper or correct to have a mandatory bill which requires mandatory spending, but discretionary funding that's available. And that is exactly what this new Democrat majority is doing. They are saying we would be absolutely required, mandatory, to spend the money, but discretionary as to whether we're really serious about providing that or not. And I believe that that is a serious question that comes under question today about the serious nature of the policy of this.

I don't attack the underlying legislation at all. The legislation does not bother me. I've supported this for years. That's what will be the underpinning of making our country stronger and better and preparing us for what may be in our future. But you can't require something and then not provide the money, especially under PAYGO rules that you had initiated yourself.

So this is simply a debate that the new Democrat majority is having within itself about whether they're really serious about their opportunity to bring to the table serious policy issues that face this great Nation.

Mr. Speaker, at this time, I would like to yield 5 minutes to the gentleman from Georgia, Dr. PRICE.

(Mr. PRICE asked and was given permission to revise and extend his remarks.)

Mr. PRICE of Georgia. Mr. Speaker, I appreciate my colleague from Texas and his leadership on this issue.

Mr. Speaker, I rise to oppose this remarkable rule, this martial-law rule.

Mr. Speaker, as you likely know, the new majority is becoming much more creative with their rule writing, and frankly it would be humorous if it weren't so serious.

At the beginning of this Congress, this new majority promised us a fair and an open process, but again the majority has failed to live up to that promise. Speaker PELOSI said, ''Because the debate has been limited and Americans' voices silenced by this restrictive rule, I urge my colleagues to vote against the rule.'' That's what she said before the election last year. Well, I agree with the Speaker, we ought to vote against this restrictive rule.

Chairman LOUISE SLAUGHTER of the Rules Committee said before, ''If we want to foster democracy in this body, we should take the time and the thoughtfulness to debate all legislation under an open rule. An open process should be the norm and not the exception.'' Well, I agree, Mr. Speaker. Now, is that a broken promise, or is it political expediency?

Democrat Caucus Chairman RAHM EMANUEL said before the election, ''Let's have an up-or-down vote. Don't be scared. Don't hide behind some little rule. Come on out here. Put it on the table, and let's have a vote.'' Well, Mr. Speaker, I agree.

Mr. Speaker, there were five amendments in total that were submitted to the Rules Committee last night. Two were made in order. What's the rush, Mr. Speaker? Which idea was so scary that the new majority decided to shut down debate? In the wake of a terrorist attack, as a result of this legislation, the liability of the American taxpayer is over $100 billion. So this legislation represents a dramatic increase in exposure to the taxpayer. And that may be appropriate.

I offered an amendment that would have allowed for appropriate PAYGO rules to make certain that we funded this bill. It went down by a partisan vote. My amendment would have protected the taxpayer dollars of hard-working Americans. There would be real offsets, a commonsense approach. If there is to be a taxpayer subsidy, as good stewards of the American hard-earned taxpayer dollars, we should provide the specific spending decrease to offset any new spending required by this legislation. Instead, Mr. Speaker, we get a budget gimmick that many of my friends and I believe is likely unconstitutional.

And that's not only the opinion of those on our side of the aisle. I have here a letter to Speaker PELOSI and Majority Leader HOYER from the office of Congressman ACKERMAN, a respected Member on the other side, who said, ''It is our strong belief that making the entire program contingent on Congress passing a second piece of legislation completely undermines the intent and the desired effect of the legislation.'' Not only unconstitutional, Mr. Speaker, but irresponsible.

Well, welcome to the theater of the absurd. Only in Washington would someone believe that requiring an additional vote at some point in the future for Congress to be able to release funds, where PAYGO won't apply, that it would diminish the cost to the hard-earned American taxpayer, or even that it's possible to do so.

Mr. Speaker, rules aren't rules if you only follow them when you want to. The Democrats promised to use PAYGO rules for everything. Instead, they're picking and choosing when they do so. At home, we call that breaking a rule and breaking a promise. Fiscal responsibility shouldn't just be something that we trump out there during campaigns and on the campaign trail.

What idea, what amendment was so scary that it inspired this incredibly draconian and restrictive rule? I urge my colleagues not to be scared. Don't hide behind, as Mr. EMANUEL said, some little rule. Vote ''no'' on this rule so we can have real PAYGO, real fiscal responsibility on this legislation. The American people deserve no less.

Mr. ARCURI. Mr. Speaker, the gentleman from Georgia asks, What is the

rush? He then talks about the theater of the absurd. What I find to be absurd is the fact that we are doing everything that we possibly can to try to prevent this legislation from being passed.

This is critical legislation. This is important not just to New Yorkers, this is important to the entire country. This is a critical piece of legislation that must get passed, and the steps that we are taking today are necessary if we are going to create the stability in business that is necessary to continue and allow our economy to grow.

I don't think it's absurd for the people who were there on 9/11. I don't think it's absurd for the insurance companies that now want to begin to insure the businesses and buildings in New York City. Oh, no, this is not absurd at all. This is the business of Congress. This is what we do, and this is what we do best.

Mr. Speaker, I now yield 5 minutes to the gentleman from New York (Mr. ACKERMAN).

Mr. ACKERMAN. I thank the other gentleman from New York.

Mr. Speaker, there are equities on both sides of this issue.

First of all, I think that we all have to and do understand that in order for any major development project to go forward, developers have to put together a plan, they have to put together their financing. Financing has to be secured in order for financing to be assured. Insurance has to be issued for any major project to go forward. There is no insurer that I can think of that would put $10 billion on the line without some backup in this day and age by the Federal Government, and I think that we're all pretty much in agreement to that.

In this argument of what to do on this rule and how to proceed, there are equities on both sides. It has been my view that the first thing that we should do is fix the rule so that in case this country is under a terrorist attack anywhere in the country, and this is not just New York City, we've been attacked, we've been attacked already, but anywhere in the country where a terrorist attack involving huge amounts of money, that the Federal Government would step in and we would not worry about the budget and the bottom line and balancing. Any city, any town, any State, any American community deserves to know that if America is attacked, and attacked in their city, in their neighborhood, in their community, that America stands behind them and will help make them whole and help put them back together again.

So it makes tremendous sense that the rule on PAYGO that was instituted and put into the rules of this House be made to accommodate the situation that says, in the case of war and in the case of a terrorist attack, nothing is going to stop us from moving forward, doing the business of America and assuring the American people.

My friends on the Republican side understand that, and they were helping to try to put this together. But the approach that we have taken up until this very moment, and, that is, putting the bill forward and then looking to find a fix later on down the road in my view was putting the horse in back of the cart. That has to be fixed, and that has to be addressed.

I originally came down here with the intent of opposing the rule, opposing the rule not because I oppose the bill, because I serve on the Financial Services Committee and worked very hard under the leadership and tutelage of Chairman FRANK who has done an immense job together with our Republican colleagues on the committee to bring a great bill to the floor only to find that it was subject to PAYGO.

I've come to the conclusion, Mr. Speaker, that we should not be looking to sidestep PAYGO. We should not be looking to make an exception to PAYGO. We should not be looking to work around PAYGO. What we should be doing is bringing common sense to the process and amending the PAYGO rules so that in the case of a terrorist attack, PAYGO is not applicable, not that we make an end run around it.

In the last few moments, Mr. Speaker, I have, after consultation with the majority leader, received a letter from him, and he has been in meetings with the Speaker of the House on this up until this very moment. And those who have intended to oppose the rule have received in writing from the majority leader, after consultation with the Speaker, an assurance in writing in this letter to us that this process will not go forward in its final form for a second vote in the House until we not sidestep PAYGO, but address the issue of PAYGO and make it right so that it makes common sense to the House and to the American people.

I have that assurance, Mr. Speaker, that this process will be fixed and that we are engaged in an ongoing process, that this vote will not be the final step, that the vote after the rule on the bill will not be final, that this bill will not be brought before us in the conference, that we will reverse and put the horse in front of the cart.

□ 1115

I would urge those with whom I have conferred, New Yorkers and others who were very, very concerned about this process, that with the assurance of the Speaker of the House and the majority leader of the House with whom I have worked for 25 years and whose word is gold, that we will bring common sense to this process and fix it before this process is through.

Mr. SESSIONS. Mr. Speaker, I appreciate the gentleman, once again, another speaker from our friends on the Democrat side, talking with us about how they are going to fix it. We appreciate that.

That is what we are asking for today. The best I can tell you is that the Republican Party is in favor of fixing it. We believe the best way to do it is on the floor of the House right now, because right now we could fix it where all the Members will understand what the ramifications are. The ramifications are either that we are going to say that terrorist attacks don't apply under PAYGO rules or that terrorist attacks would be in fine print, that now perhaps the Democrat majority wants to put in that all this spending applies but perhaps not under certain circumstances. I think we could craft a deal here.

But now what the gentleman is asking us to do is ''just trust me.'' Well, the first thing I would like to do is get a copy of the letter. It would be appropriate for me to ask for that. I know the gentleman, Mr. ACKERMAN, does not oppose my getting a copy of that letter. But what we are now being told is, ''now trust us that it will be brought back in a forum where there is debate, but it is either an up or down vote.'' We can't change that decision, nor can any other Member of this body change that. We have heard enough people talk today about how what is happening is wrong, should not happen, is bad policy. We ought to fix it today here on the floor if we are going to move forward and not say, ''trust me, trust me, wait for fine print or disagreement later.''

I appreciate the gentleman, Mr. ACKERMAN. I thought it was not only very nice what he did but well spoken, and I appreciate the gentleman very much.

Mr. Speaker, I yield 5 minutes to my friend, the gentleman from New York (Mr. KING).

Mr. KING of New York. Mr. Speaker, I thank the gentleman from Texas for yielding.

I rise in strong support of the underlying legislation and certainly with very strong questions and reservations about the rule. Like Mr. ACKERMAN, I certainly came to the floor intending to oppose the rule. I will study the letter which Mr. ACKERMAN obtained from the majority leader. I agree with Mr. SESSIONS that this is a very uncertain way to proceed, relying on a promise from a letter. Not that I, in any way, question the intent to follow through on the promise, but again, how that could be interpreted, what the final language will be, does raise serious issues.

Having said that, I commend Mr. ACKERMAN for his efforts. I do believe it is important that this process continue to go forward.

The reason I support the underlying legislation, Mr. Speaker, is that this is not a New York issue, even though it is often focused that way because of the fact that there have been two major terrorist attacks on New York City, but it truly is a national issue. I want to commend Chairman FRANK for his efforts at the committee level. I also want to emphasize that this was a bipartisan vote which voted this bill out of committee. I particularly appreciate

the fact that, in the committee, an amendment was offered by myself and Mr. ACKERMAN which extends TRIA 15 years, passed by a bipartisan vote.

I know that, certainly on my side of the aisle, a number of Members are concerned about the reason that the 15-year term is essential. The fact is that any significant project is going to be of 15 years' duration. Both the preliminary work and the construction itself is going to go to 15 years. The insurance money, for instance, in New York, where they are attempting to rebuild Ground Zero, would not be available at this time unless TRIA is extended. And also the insurers have the certainty that TRIA will be there for the 15 years, for the duration of the project.

I have to emphasize that there will be not one nickel spent of this money unless New York or Chicago or Los Angeles or any other city in the country is attacked by terrorists. So if any city were attacked, we know the government would step in. Why not have that precaution now? Why not give the insurers the certainty, and the municipalities the certainty, so they can go forward with this development? Otherwise, we are allowing the terrorists to set the terms and conditions. We are letting them determine what is going to be built and not rebuilt. If this 15-year extension does not go forward, if TRIA is not extended, the reality is that there will not be a rebuilding of Ground Zero. If Ground Zero is not rebuilt, then this is a magnificent victory for a horrible, horrible force, Islamic terrorism. So we should be the ones determining what our economic security is and what our homeland security is. Passage of TRIA is an essential component of that.

As the former chairman of the Homeland Security Committee and its ranking member, Mr. Speaker, I am very much aware how New York and other cities in other parts of our country are in the crosshairs of Islamic terrorism. We know that attacks are inevitable. Whether or not they are successful is another story, but certainly attempted attacks are inevitable. I believe it is essential that no matter what part of the country you are from, you have the assurance that if, God forbid, you are attacked, that there will be insurance in place for you to rebuild. Because otherwise, you are not going to find insurers stepping forward. Places like New York, which was attacked, will not receive insurance that it needs to go forward. And the terrorists will have scored and attained not just the victory they attained on September 11 where almost 3,000 people were murdered, but they will have the additional victory in that the area that they attacked will not be rebuilt.

It could be New York. As I said, it was New York in 1993. It was New York in 2001. It could be any one of a number of other cities in the future. So let us protect ourselves in the ultimate essence of homeland security and have a complete component of security, and TRIA is essential to that.

Mr. Speaker, I urge adoption of the underlying legislation. I look forward to examining the letter which Mr. ACKERMAN procured and see what that signifies for the future. But the reality is that we have to have the absolute assurance. We cannot be relying on a vote sometime in the future. The government itself could be attacked. The Capitol may not be here. There may not be a quorum of Members attainable. We have to have that absolute assurance in place now.

With that, again, I thank Chairman FRANK. I thank, certainly, Mr. SESSIONS for his courtesy. I thank Mr. ACKERMAN for his efforts. I also thank Ranking Member BACHUS for his cooperation and courtesy throughout this hearing.

Mr. ARCURI. Mr. Speaker, I thank my friend and colleague from New York (Mr. KING) for his words. He has worked hard on the TRIA legislation, and we appreciate that.

Mr. Speaker, I yield 3 minutes to the gentleman from Massachusetts (Mr. CAPUANO).

Mr. CAPUANO. Mr. Speaker, reasonable people have differences of opinion on the base bill. There are a lot of things in here that I think different people can have different opinions on, the 15-year time limits and the triggers in the deductibles. A lot of them, almost all of them, are reasonable best guesses based on experience, and that is it. They are open to discussion. They are open to debate. There is no definitive answer as to which one is right. This bill is the classic example of compromise upon compromise to try to get to a bill that as many people can support and feel comfortable with as possible.

If the debate here right now or later on is on the base bill, that is hard to argue. That is a gut feeling. There are no definitives and no real answers. But I will tell you that when the argument turns to fiscal responsibility and there is this false argument that someone is more fiscally responsible than someone else, it bothers me. It bothers me a lot, because I think that is beginning to get into the great lie to the American people: ''We are more responsible than you. We are more responsible. We do this; you do that.'' Well, the truth is, not a single penny of taxpayers' money will be paid out in this bill under this rule unless Congress acts again. Not one penny.

Now, I understand that some people find that uncomfortable. I respect that. If there is another route to take, fine. I am open to discussion. I am open to the proposals. But to pretend this bill is somehow going to spend taxpayers' money when it is not is ludicrous. To pretend that people here are more fiscally responsible than others when they are not bothers me even more.

We had one major vote on PAYGO. One. And that was November 14, 2002, when the Republican-led House put forth a bill on this floor that basically gutted and terminated PAYGO. Only 19 Members of this House voted against that bill. Not a single Republican voted against it. Not one. And it gutted and killed PAYGO, according to CRS, to the tune of $560 billion. That was real money and real PAYGO that threatened a real sequestration over 5 years. Yet, the Republican-led House then, after the 9/11 attack, while we were in the middle of war, decided PAYGO was not important then. They killed it. If it wasn't important then, and yet today we are taking an action that we guarantee that no taxpayer money gets spent without additional action by this House, then I don't understand the logic. I see it as nothing but hypocritical.

Mr. SESSIONS. Mr. Speaker, you know, I do appreciate my good friend, the gentleman from Massachusetts, coming in and arguing, but his side has already given in on this point. They have already conceded that they don't like the way the bill is, the self-executing rule. There is already agreement on his side, ''Whoa, this is wrong. We don't agree with this. We will agree to fix it.''

So, I love the gentleman from Massachusetts, he and I are very good friends, but they have already conceded that point. They have already said, ''We think there could be a better way to do it. We agree to fix it.'' So what did we say on this side? ''Thank you very much, Mr. ACKERMAN. We appreciate this. That is what we have been asking for. We are pleased that we got it.''

I wish we had the agreement here today. I wish we knew what that deal was going to be before you brought the bill to the floor. That's why we held off in the Rules Committee for an extra day waiting for a better answer. Didn't get it, get to the floor.

I would say to my good friends on this side, if you want us to be a better minority, you are going to have to be a better majority. We took seriously what Speaker PELOSI said, ''honest, open, ethical Congress.'' We are still waiting for that through the Rules Committee. When she said, ''PAYGO is going to apply to everything,'' it implied that Republicans didn't do that. Then we took that at the surface of the words, not looking for fine print, not looking for how they are going to try and get out of it. So we are trying to make sure that we simply know what we are supposed to count on.

They have come to the floor today, and they have said, ''We are going to work on it.'' I am pleased we are going to do that. I am simply saying that it should have been done before it got here. That is sloppy.

Mr. Speaker, at this time, I have no additional speakers on the rule. I yield to the gentleman from New York to run down his time, then I will make my closing statement.

Mr. ARCURI. I have no further speakers, Mr. Speaker.

Mr. SESSIONS. Mr. Speaker, I will be asking Members to oppose the previous question so that I may amend the

rule to allow for the consideration of H. Res. 479, a resolution that I have not heard talked about today but the concepts are in that that I will call the ''Earmark Accountability Rule.''

At the beginning of this Congress, a number of promises were made to the American people about the Democrats' supposedly new and improved earmark rules.

□ 1130

As the Congress has worn on, however, I have noticed that while the Democrats' rule changes definitely sound good, they have not really lived up to their promise and have not really accomplished much, since the majority has repeatedly turned their head the other way when it comes to their actual enforcement.

I acknowledge that the majority has given into the minority demands for enforcement of their own rules a handful of times when it comes to appropriations conference reports. Unfortunately, we continue to see non-disclosed earmarks in all sorts of bills, also.

This rules change would simply allow the House to debate openly and honestly the validity and accuracy of earmarks contained in all bills, not just appropriations bills. If we defeat the previous question, we can address that problem today and restore this Congress' nonexistent credibility when it comes to enforcement of its rules, like we have seen once again today.

Mr. Speaker, I ask unanimous consent to have the text of the amendment and extraneous material appear in the RECORD just prior to the vote on the previous question.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Texas?

There was no objection.

Mr. SESSIONS. Mr. Speaker, I yield back the balance of my time.

Mr. ARCURI. Mr. Speaker, I am troubled by the fact that today, everything we hear from the other side is smoke and mirrors. They want to talk about everything except what we are here to talk about today, and that is the rule on the TRIA legislation.

My friend from Texas infers that the Rules Committee is not open, honest and ethical. Well, I resent that. I think we are very open, we are honest, and we are very ethical. He knows that, and he shouldn't put petty partisan politics ahead of what we are here today to do, and that is to pass a rule on TRIA legislation.

Protecting the security and safety of America is without question our top priority and the reason that we are here in Congress as Members of this institution. The horrible terrorist attacks of September 11, 2001, had a devastating effect on so many people in this country; not just New Yorkers, but people all over this country.

It also had a devastating economic impact on the commercial insurance market. Many primary insurers stopped writing policies. Special guidelines were instituted when insuring buildings thought to be likely terrorist targets and other properties surrounding them. Reinsurers, those companies that insure the insurance companies, excluded terrorist events from coverage altogether.

To address this market failure, Congress passed the Terrorism Risk Insurance Act, and that was under the Republican Congress, because it was the right thing to do. And we will continue to do the right thing here today.

TRIA has been a success. Primary insurers are able to write policies and business owners are able to obtain coverage. Stability was restored to this vital market. If we do not act now to extend TRIA, this program will expire and we will be back where we were following the September 11 attacks.

H.R. 2761 extends TRIA by 15 years to provide added certainty to this vital sector of our economy that a mere 2-year extension cannot provide. The bill also lays the groundwork for the inclusion of coverage for nuclear, biological, chemical and radiological terrorist acts, while at the same time allowing for an exemption for small insurers that would be unfairly impacted by this necessary expansion.

The circumstances before us are unlike anything we have confronted in our Nation's history. We must not allow terrorist attacks to force valuable businesses to fail because they cannot afford insurance.

Mr. Speaker, I am proud to stand here today as a member of the new Democratic majority, watching out for the interests of our Nation's business community by providing much-needed predictability in the terrorism risk insurance market.

Mr. Speaker, I urge a ''yes'' vote on this rule and on the previous question.

The material previously referred to by Mr. SESSIONS is as follows:

AMENDMENT TO H. RES. 660 OFFERED BY MR. SESSIONS OF TEXAS

At the end of the resolution, add the following:

SEC. 3. That immediately upon the adoption of this resolution the House shall, without intervention of any point of order, consider the resolution (H. Res. 479) to amend the Rules of the House of Representatives to provide for enforcement of clause 9 of rule XXI of the Rules of the House of Representatives. The resolution shall be considered as read. The previous question shall be considered as ordered on the resolution to final adoption without intervening motion or demand for division of the question except: (1) one hour of debate equally divided and controlled by the chairman and ranking minority member of the Committee on Rules; and (2) one motion to recommit.

(The information contained herein was provided by Democratic Minority on multiple occasions throughout the 109th Congress.)

THE VOTE ON THE PREVIOUS QUESTION: WHAT IT REALLY MEANS

This vote, the vote on whether to order the previous question on a special rule, is not merely a procedural vote. A vote against ordering the previous question is a vote against the Democratic majority agenda and a vote to allow the opposition, at least for the moment, to offer an alternative plan. It is a vote about what the House should be debating.

Mr. Clarence Cannon's Precedents of the House of Representatives, (VI, 308–311) describes the vote on the previous question on the rule as ''a motion to direct or control the consideration of the subject before the House being made by the Member in charge.'' To defeat the previous question is to give the opposition a chance to decide the subject before the House. Cannon cites the Speaker's ruling of January 13, 1920, to the effect that ''the refusal of the House to sustain the demand for the previous question passes the control of the resolution to the opposition'' in order to offer an amendment. On March 15, 1909, a member of the majority party offered a rule resolution. The House defeated the previous question and a member of the opposition rose to a parliamentary inquiry, asking who was entitled to recognition. Speaker Joseph G. Cannon (R–Illinois) said: ''The previous question having been refused, the gentleman from New York, Mr. Fitzgerald, who had asked the gentleman to yield to him for an amendment, is entitled to the first recognition.''

Because the vote today may look bad for the Democratic majority they will say ''the vote on the previous question is simply a vote on whether to proceed to an immediate vote on adopting the resolution . . . [and] has no substantive legislative or policy implications whatsoever.'' But that is not what they have always said. Listen to the definition of the previous question used in the Floor Procedures Manual published by the Rules Committee in the 109th Congress, (page 56). Here's how the Rules Committee described the rule using information from Congressional Quarterly's ''American Congressional Dictionary'': ''If the previous question is defeated, control of debate shifts to the leading opposition member (usually the minority Floor Manager) who then manages an hour of debate and may offer a germane amendment to the pending business.''

Deschler's Procedure in the U.S. House of Representatives, the subchapter titled ''Amending Special Rules'' states: ''a refusal to order the previous question on such a rule [a special rule reported from the Committee on Rules] opens the resolution to amendment and further debate.'' (Chapter 21, section 21.2) Section 21.3 continues: ''Upon rejection of the motion for the previous question on a resolution reported from the Committee on Rules, control shifts to the Member leading the opposition to the previous question, who may offer a proper amendment or motion and who controls the time for debate thereon.''

Clearly, the vote on the previous question on a rule does have substantive policy implications. It is one of the only available tools for those who oppose the Democratic majority's agenda and allows those with alternative views the opportunity to offer an alternative plan.

Mr. ARCURI. Mr. Speaker, I yield back the balance of my time, and I move the previous question on the resolution.

The SPEAKER pro tempore. The question is on ordering the previous question.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

Mr. ARCURI. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on questions previously postponed.

Votes will be taken in the following order: on approving the Journal, de novo; on ordering the previous question on H. Res. 660, by the yeas and nays; on adopting H. Res. 660, if ordered.

The first electronic vote will be conducted as a 15-minute vote. Remaining electronic votes will be conducted as 5-minute votes.

THE JOURNAL

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the unfinished business is the question on agreeing to the Speaker's approval of the Journal.

The question is on the Speaker's approval of the Journal.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

Mr. ARCURI. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The vote was taken by electronic device, and there were—yeas 228, nays 192, not voting 12, as follows:

[Roll No. 878]

YEAS—228

Abercrombie
Ackerman
Andrews
Arcuri
Baird
Baldwin
Bean
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Brown, Corrine
Buchanan
Butterfield
Cannon
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chabot
Chandler
Clarke
Clay
Cleaver
Clyburn
Coble
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis, Lincoln
Davis, Tom
DeGette
Delahunt
DeLauro
Dent
Dicks
Dingell
Doggett
Doyle
Edwards
Ellison
Emanuel
Engel
Eshoo
Etheridge
Farr
Fattah
Filner
Forbes
Fortenberry
Frank (MA)
Giffords
Gillibrand
Gonzalez
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hooley
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson (IL)
Johnson, E. B.
Jones (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick
Kind
Kingston
Klein (FL)
Kucinich
Kuhl (NY)
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
LaTourette
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Marshall
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McDermott
McGovern
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Miller, George
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murtha
Nadler
Napolitano
Neal (MA)
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Paul
Payne
Perlmutter
Pomeroy
Porter
Price (NC)
Rahall
Rangel
Reyes
Richardson
Rodriguez
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Sires
Skelton
Smith (NJ)
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Sutton
Tanner
Tauscher
Taylor
Thompson (MS)
Tierney
Towns
Udall (CO)
Udall (NM)
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Wexler
Wilson (OH)
Woolsey
Wu
Wynn
Yarmuth

NAYS—192

Aderholt
Akin
Alexander
Altmire
Bachmann
Bachus
Baker
Barrett (SC)
Barrow
Bartlett (MD)
Barton (TX)
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono
Boozman
Boustany
Brady (TX)
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cantor
Capito
Carter
Castle
Cole (OK)
Conaway
Crenshaw
Culberson
Davis (KY)
Davis, David
Deal (GA)
DeFazio
Diaz-Balart, L.
Diaz-Balart, M.
Donnelly
Doolittle
Drake
Dreier
Duncan
Ehlers
Ellsworth
Emerson
English (PA)
Everett
Fallin
Feeney
Ferguson
Flake
Fossella
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Gerlach
Gingrey
Gohmert
Goode
Goodlatte
Gordon
Granger
Graves
Hall (TX)
Hastert
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Hill
Hobson
Hoekstra
Hulshof
Hunter
Inglis (SC)
Issa
Johnson, Sam
Jones (NC)
Jordan
Keller
King (IA)
King (NY)
Kirk
Kline (MN)
LaHood
Lamborn
Latham
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
McCarthy (CA)
McCaul (TX)
McCotter
McCrery
McHenry
McHugh
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Mitchell
Moran (KS)
Murphy, Tim
Musgrave
Myrick
Neugebauer
Nunes
Pearce
Pence
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Price (GA)
Pryce (OH)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Reynolds
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Sali
Saxton
Schmidt
Sensenbrenner
Sessions
Shadegg
Shays
Shimkus
Shuler
Shuster
Simpson
Smith (NE)
Smith (TX)
Souder
Stearns
Stupak
Sullivan
Tancredo
Terry
Thompson (CA)
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walberg
Walden (OR)
Walsh (NY)
Wamp
Weldon (FL)
Weller
Westmoreland
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)
Young (FL)

NOT VOTING—12

Allen
Baca
Braley (IA)
Carney
Cubin
Davis, Jo Ann
Garrett (NJ)
Gilchrest
Jindal
Johnson (GA)
Knollenberg
Slaughter

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised 2 minutes remain in this vote.

□ 1159

Mr. KUHL of New York changed his vote from ''nay'' to ''yea.''

So the Journal was approved.

The result of the vote was announced as above recorded.

PROVIDING FOR CONSIDERATION OF H.R. 2761, TERRORISM RISK INSURANCE REVISION AND EXTENSION ACT OF 2007

The SPEAKER pro tempore. The unfinished business is the vote on ordering the previous question on House Resolution 660, on which the yeas and nays were ordered.

The Clerk read the title of the resolution.

The SPEAKER pro tempore. The question is on ordering the previous question.

This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 224, nays 197, not voting 11, as follows:

[Roll No. 879]

YEAS—224

Abercrombie
Ackerman
Altmire
Andrews
Arcuri
Baca
Baird
Baldwin
Bean
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown, Corrine
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Clarke
Clay
Cleaver
Clyburn
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis, Lincoln
DeFazio
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Donnelly
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Eshoo
Etheridge
Farr
Fattah
Filner
Frank (MA)
Giffords
Gillibrand
Gonzalez
Gordon
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hill
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hooley
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick
Kind
Klein (FL)
Kucinich
Langevin
Lantos
Larsen (WA)
Larson (CT)
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Marshall
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McDermott
McGovern
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Miller, George
Mitchell

Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murtha
Nadler
Napolitano
Neal (MA)
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Payne
Perlmutter
Peterson (MN)
Pomeroy
Price (NC)
Rahall
Rangel
Reyes
Richardson
Rodriguez
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Shuler
Sires
Skelton
Slaughter
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stupak
Sutton
Tanner
Tauscher
Taylor
Thompson (CA)
Thompson (MS)
Tierney
Towns
Udall (CO)
Udall (NM)
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Wexler
Wilson (OH)
Woolsey
Wu
Wynn
Yarmuth

NAYS—197

Aderholt
Akin
Alexander
Bachmann
Baker
Barrett (SC)
Barrow
Bartlett (MD)
Barton (TX)
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono
Boozman
Boustany
Brady (TX)
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Cantor
Capito
Carter
Castle
Chabot
Coble
Cole (OK)
Conaway
Crenshaw
Culberson
Davis (KY)
Davis, David
Davis, Tom
Deal (GA)
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Doolittle
Drake
Dreier
Duncan
Ehlers
Emerson
English (PA)
Everett
Fallin
Feeney
Ferguson
Flake
Forbes
Fortenberry
Fossella
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gingrey
Gohmert
Goode
Goodlatte
Granger
Graves
Hall (TX)
Hastert
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Hobson
Hoekstra
Hulshof
Hunter
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jones (NC)
Jordan
Keller
King (IA)
King (NY)
Kingston
Kirk
Kline (MN)
Kuhl (NY)
LaHood
Lamborn
Lampson
Latham
LaTourette
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
McCarthy (CA)
McCaul (TX)
McCotter
McCrery
McHenry
McHugh
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Moran (KS)
Murphy, Tim
Musgrave
Myrick
Neugebauer
Nunes
Paul
Pearce
Pence
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Porter
Price (GA)
Pryce (OH)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Reynolds
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Sali
Saxton
Schmidt
Sensenbrenner
Sessions
Shadegg
Shays
Shimkus
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Souder
Stearns
Sullivan
Tancredo
Terry
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walberg
Walden (OR)
Walsh (NY)
Wamp
Weldon (FL)
Weller
Westmoreland
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)
Young (FL)

NOT VOTING—11

Allen
Bachus
Carney
Cubin
Davis, Jo Ann
Engel
Gilchrest
Jindal
Johnson (GA)
Jones (OH)
Knollenberg

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised there are 2 minutes remaining in this vote.

□ 1206

Mr. WELCH of Vermont changed his vote from ''nay'' to ''yea.''

So the previous question was ordered.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the resolution.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. SESSIONS. Mr. Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. This will be a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 223, noes 195, not voting 14, as follows:

[Roll No. 880]

AYES—223

Abercrombie
Ackerman
Andrews
Arcuri
Baca
Baird
Baldwin
Barrow
Bean
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown, Corrine
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Clarke
Clay
Cleaver
Clyburn
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis, Lincoln
DeFazio
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Donnelly
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Eshoo
Etheridge
Farr
Fattah
Filner
Frank (MA)
Giffords
Gillibrand
Gonzalez
Gordon
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hill
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hooley
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick
Kind
Klein (FL)
Kucinich
Langevin
Lantos
Larsen (WA)
Larson (CT)
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Marshall
Matheson
McCollum (MN)
McDermott
McGovern
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Miller, George
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murtha
Nadler
Napolitano
Neal (MA)
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Payne
Perlmutter
Peterson (MN)
Pomeroy
Price (NC)
Rahall
Rangel
Reyes
Richardson
Rodriguez
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shea-Porter
Sherman
Shuler
Sires
Skelton
Slaughter
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stupak
Sutton
Tanner
Tauscher
Taylor
Thompson (CA)
Thompson (MS)
Tierney
Towns
Udall (CO)
Udall (NM)
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Wexler
Wilson (OH)
Woolsey
Wu
Wynn
Yarmuth

NOES—195

Aderholt
Akin
Alexander
Altmire
Bachmann
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Barton (TX)
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono
Boozman
Boustany
Brady (TX)
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Cantor
Capito
Carter
Castle
Chabot
Coble
Cole (OK)
Crenshaw
Culberson
Davis (KY)
Davis, David
Davis, Tom
Deal (GA)
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Doolittle
Drake
Dreier
Duncan
Ehlers
Emerson
English (PA)
Everett
Fallin
Feeney
Ferguson
Flake
Forbes
Fortenberry
Fossella
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gingrey
Gohmert
Goode
Goodlatte
Granger
Graves
Hall (TX)
Hastert
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Hobson
Hoekstra
Hulshof
Hunter
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jones (NC)
Jordan
Keller
King (IA)
King (NY)
Kingston
Kirk
Kline (MN)
Kuhl (NY)
LaHood
Lamborn
Lampson
Latham
LaTourette
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
McCarthy (CA)
McCaul (TX)
McCotter
McCrery
McHenry
McHugh
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Moran (KS)
Murphy, Tim
Musgrave
Myrick
Neugebauer
Nunes
Paul
Pearce
Pence
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Porter
Price (GA)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Reynolds
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Sali
Saxton
Schmidt
Sensenbrenner
Sessions
Shadegg
Shays
Shimkus
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Souder
Stearns
Tancredo
Terry
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walberg
Walden (OR)
Walsh (NY)
Wamp
Weldon (FL)
Weller
Westmoreland
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)
Young (FL)

NOT VOTING—14

Allen
Carney
Conaway
Cubin
Davis, Jo Ann
Engel
Gilchrest
Jindal
Johnson (GA)
Knollenberg
Matsui
McCarthy (NY)
Pryce (OH)
Sullivan

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised there are 2 minutes remaining in this vote.

□ 1214

Mr. ALTMIRE changed his vote from ''aye'' to ''no.''

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. FRANK of Massachusetts. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days within which to revise and extend their remarks on H.R. 2761 and to insert extraneous material therein.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

TERRORISM RISK INSURANCE REVISION AND EXTENSION ACT OF 2007

The SPEAKER pro tempore. Pursuant to House Resolution 660 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the state of the Union for the consideration of the bill, H.R. 2761.

□ 1215

IN THE COMMITTEE OF THE WHOLE

Accordingly, the House resolved itself into the Committee of the Whole House on the state of the Union for the consideration of the bill (H.R. 2761) to extend the Terrorism Insurance Program of the Department of the Treasury, and for other purposes, with Mr. ISRAEL in the chair.

The Clerk read the title of the bill.

The CHAIRMAN. Pursuant to the rule, the bill is considered read the first time.

The gentleman from Massachusetts (Mr. FRANK) and the gentleman from Alabama (Mr. BACHUS) each will control 30 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. FRANK of Massachusetts. Mr. Chairman, this is a continuation of a program that the Congress adopted in one of the previous Congresses to provide insurance in case of a terrorist attack. We had, obviously, the terrible murderous attack on America in 2001.

Substantial damage was done. Obviously, the overwhelming cost of that was in the human lives caused by these murderers, but we also had property damage. And I believe that it is unrealistic to think, and in fact inappropriate to urge, that the private insurance market, which functions very well in this country and serves us well, that that ought to be used in response to terrorism. We bring a bill forward that would provide both for life and property insurance from the Federal Government worked out in various ways.

There are two arguments for continuing this on an ongoing basis. Everybody agrees that it needs to be extended for a while. Some have said phase it out, let the private market ultimately take it over. I believe there are two reasons why that is not a good idea.

First, virtually no entities that are in the private insurance market believe that the private market could handle this well. Not only do the insurers believe that, but the customers of the insurance believe it. And primarily, by the way, the customers here are commercial real estate developers. People who are going to build large commercial buildings with tens, hundreds of millions of dollars in construction costs cannot build without a bank loan, and the banks will not lend and would not be allowed to lend by the regulators without fully insuring against all risks, including the risks of the terrorism that we wish were not around but clearly still is.

We do not believe, based on extensive conversations with virtually everyone in the marketplace, that this will work. In fact, I submit for printing in the RECORD a letter from the head of Goldman Sachs in 2005, that very important financial institution, clearly an entity that knows a great deal about the market. And in 2005, only 2 years ago, after we had TRIA for a while and the question was coming up about whether or not to continue it, he wrote to the gentleman from Louisiana (Mr. BAKER), then Chair of the Capital Market Subcommittee, that:

''Current data suggests that reinsurance, and consequently insurance, participation in the terrorism insurance market will decline if the Federal backstop is left to expire.

''Some have suggested that private markets for terrorism can successfully utilize risk transfer mechanisms such as catastrophe bonds.

''There is no evidence to suggest that the rating agencies or capital markets investors will be able to quantify the risk.''

And what he says is that he does not believe the market can do this.

THE GOLDMAN SACHS GROUP, INC.,
New York, NY, July 26, 2005.

Hon. RICHARD BAKER,
Chairman, Subcommittee on Capital Markets, Insurance and Government Sponsored Enterprises, House of Representatives, Cannon House Office Building, Washington, DC.

DEAR MR. CHAIRMAN: On behalf of The Goldman Sachs Group, lnc., a leading global investment banking, securities and investment management firm, I am writing to express my support for maintaining a federal terrorism insurance backstop.

The federal terrorism insurance program, enacted by the Terrorism Risk Insurance Act of 2002 (TRIA), has helped provide the underpinning to a robust economic recovery despite the ongoing threat of terrorism. Notwithstanding Treasury's conclusion that TRIA has achieved its original purpose, we are not aware of any meaningful evidence showing that private terrorism risk insurance or reinsurance markets have developed ample capacity to rationally price and insure against terrorism on a scale that would adequately protect our nation's economy. In fact, current data suggests that reinsurance, and consequently insurance, participation in the terrorism insurance market likely will decline significantly if the federal terrorism insurance backstop is left to expire.

Some have suggested that private markets for terrorism risk can successfully utilize risk transfer mechanisms such as catastrophe bonds (CAT bonds) that transfer risk from insurers to capital markets. Such securitization vehicles, however, represent a minor percentage of the overall insurance market and have been used mainly for natural disasters, such as earthquakes and hurricanes. There is no evidence to suggest that the rating agencies or capital markets investors will be able to more effectively quantify the risk of terrorism than insurers or reinsurers. As such, CAT bonds and other risk transfer mechanisms are unlikely to offer, at this time, the broad capacity necessary to insure America's businesses, workers and property owners against the risk of terrorism.

With less than five months remaining in the current program, American businesses soon will be forced to compete for portions of a severely constrained private insurance market and risk the possibility of being left with inadequate levels of terrorism insurance. In short, we simply cannot afford to let the private sector be economically exposed.

I appreciate your attention to this very important matter.

Sincerely,

HENRY M. PAULSON, Jr.,
Chairman and Chief Executive Officer.

The CEO of Goldman Sachs who signed this is a very distinguished expert, Henry M. Paulson, Jr. He is no longer the chief of Goldman Sachs; he is now the Secretary of the Treasury and has somewhat different views, but this is a letter that he sent in late July 2005.

So we don't think the market can handle it. But I want to argue that even if you thought the market could handle it, we shouldn't ask it to for this reason: If you insure against risk, you ultimately pass the costs along to the people who are at risk. Insurance allows you to spread that risk out among those who are at risk. But the more you are at risk, the more you pay in insurance.

If we were to adopt a purely market solution, that would mean that those parts of the country which were calculated to be likelier targets of terrorism would pay more. That is the insurance principle. If you are more likely to be the victim of terrorism, then you should pay more.

I do not think we should allow vicious fanatics who hate this country and seek to inflict severe physical damage on us to decide where it should be more expensive to do business in our country and where it should not. But if you use the private insurance mechanism, that is what you get.

There is another problem with the private insurance mechanism, not a problem, a good facet, that doesn't apply here. What you can do with private insurance is to say to these entities: You know what, if you lower your risk, we will lower your insurance costs. But people who have large office buildings cannot significantly lower their risk of being attacked by terrorists. If they could, we wouldn't want them to be. We wouldn't want people in

America in the business sector to be told, well, why don't you try to appease the terrorists so they don't blow you up. So it ought to be a public program.

Now, we have had significant debate in the committee. We had in the subcommittee and committee two full markups, an unusual degree of attention. A number of amendments were adopted from both parties. It is a different and, I believe, better bill now than it was when it was introduced. There are still some philosophical differences.

There is one issue, though, that came up after the committee consideration, and to our surprise the Congressional Budget Office said that this is going to cost a certain amount of money. I will get the estimate. I think they said $10 billion over a period of 10 years. That is a very odd thing to say. A terrorist attack will cost hundreds of billions if it happens; it will cost nothing if it doesn't. They apparently used some calculation of probability, which I think is in itself kind of dubious. Nobody, I think, can realistically talk about the probability of a terrorist attack, to give us the number that it will cost $3.5 billion over 5 years and $8.4 billion over 10 years.

One thing we know for sure is that these estimates are wrong. It will either cost a lot more, or nothing. CBO did its job, I don't think very well. Maybe that is because of the constraints they operate under. I don't make a personal criticism of them. But we have this PAYGO rule.

I will say that my own preference as an individual Member would have been to grant an emergency waiver, because if a terrorist attack is an emergency, then we shouldn't have that in there. I do not represent the thinking of the majority as of now on this or the Democratic leadership. That is an open question to evolve. So we did the next best thing, which is to adopt a set of procedures to deal with what will happen if the Federal Government has to make a payout under this.

I will say that I think that was a good effort, given the time frame. And I think it is important, given the potential expiration or the expiration date, that we should move forward, and maybe it will encourage our colleagues across the Capitol to act.

I do not believe that what we have in here will be the final answer. We have one possibility: Maybe a consensus will develop on a waiver. I can't say that I have confidence in that, but I certainly will advocate for it. If we can't get a waiver, we will within the framework of the PAYGO requirement, $3 billion over 5 years, try to work something out. And I know that is what the Democratic leadership has assured the Members from New York in particular, that they will do their best within the context of PAYGO to work this out. And I believe we can improve on where we are. We will reduce the risk that there won't be payment to the minimum amount possible, and then maybe we share that risk.

So I do not believe that what we have in this bill will be the final version. I think it is important to move this process along. I think this is as good an effort to do it as we could now. We will have to be consulting with the various parties in interest, including the cities, including the insurers, including the insured and others, and we will move forward on that. So I do believe it is very important to move forward now.

The only reason to vote against this bill at this point is not because of disagreement on some of the specifics. They will evolve as we go forward, particularly in the PAYGO response. But if you believe this is something that should be left to the market, and I do not believe that the market can or should be asked to handle terrorism. Adam Smith is one of the great intellectual contributors to thought in this world, but I don't think he knew much about terrorism, luckily for him. I do not think that the free market was adopted or is adaptable to murderous attacks of the sort we had on September 11.

So I believe this is the best we can do at this point. It is a very good bill, I believe, not perfect, with regard to the PAYGO fix, but that is something that I believe will evolve. I have every confidence that we will be able to do it better as we go forward, and I hope the bill passes.

I reserve the balance of my time.

Mr. BACHUS. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, as one of the original authors of the first TRIA legislation back in 2002, which passed this House with a strong vote, and also as a supporter of the extension in 2005, which I also cosponsored, I am disappointed that I have to rise today in opposition to the present bill. But I do so sincerely.

The whole idea of TRIA, the 2002 bill, the 2005 extension, was to create a short-term government backstop which would allow the insurance industry, the private market to adjust to the 9/11 reality.

By any objective measure, people on both sides of the aisle have said TRIA has been a success. Secretary Hank Paulson supported a TRIA which was a government backstop as the government continued to process the stepping back.

The terrorist insurance markets have stabilized. We have heard this debate, this word today of the gentleman from New York and the leadership and the Democratic Party and some of their differences. Even in correspondence which I have seen, he said terrorist insurance, the approach we have has been working. It is giving us insurance. The markets have stabilized. Policyholders are requesting and they are receiving coverage. Prices have declined. Reinsurance has become more available. The private marketplace is diversifying, and it is absorbing additional risk exposure every day.

This past July, Secretary Paulson, which, as I said, he supported TRIA, he doesn't support this legislation because it essentially preempts the private market. But he made this statement to me: It is my belief that the most efficient, lowest cost, and most innovative methods of providing terrorist risk insurance will come from the private sector.

I agree, and it is therefore that reason that I must oppose the bill before us today, because it works at cross-purposes with that whole philosophy of allowing a temporary backstop as the private market fills in and meets the need for terrorist risk insurance.

We presently have a TRIA program in place that relies on that private sector first and the government only as a backstop and, as I said, it is working very well. It is effectively creating what is a temporary assistance or a hand up, not a permanent handout. However, this bill replaces what has been a successful and temporary mechanism which has worked so well to allow the insurance marketplace to adopt to the 9/11 realities. It replaces it with legislation that, instead of scaling back the Federal backstop, it expands it greatly. It increases the government growth greatly. It increases taxpayers' exposure tremendously, so much so that we are not going to pay for it here today. We are going to disregard PAYGO. And I understand there is some private deal that may have been agreed to out of the public domain and unknown to Members. That is not how legislation should function. But it is a flawed bill that is, unfortunately, a departure from what has heretofore been a very successful bipartisan consensus effort on behalf of this Congress that we have all come together and adopted in the past.

TRIA should not be a partisan issue. Our division on this legislation reflects a philosophical difference and disagreement over how, how much and for how long middle-class America should subsidize the cost of terrorist insurance for both insurers and for urban developers.

□ 1230

And what is the taxpayer role?

I had hoped that we could consider a number of important amendments today to scale back these new Federal subsidies; i.e., taxpayer-supported guaranteed benefits. I had hoped that we could ask that the insurance companies pay a greater percentage; that they collect an increased amount. Unfortunately, the Democratic leadership has decided not to even allow a fair and free debate on these amendments.

The expanded Federal subsidies provided for in this bill are so expensive that they violate the House's budget rules. But, as I said, instead of admitting this violation, or even waiving it, which would be a more honest approach, or finding a way to pay for the costs to the taxpayers, the majority has turned to what I call a ''fantasy fix'' that mandates various terrorist coverage, but removes any certainty in the Federal payment.

Even the most ardent proponents of TRIA are opposed to this so-called solution to the PAYGO problem. One Democratic colleague that's on the floor today has made this statement which I associate myself with: ''Making the entire program contingent on Congress passing a second piece of legislation completely undermines the intent and desired effect of the legislation.'' He went on to say, and I quote, ''It would render the legislation almost completely useless.'' That's the legislation we have before us. That's it. That's what we're considering today.

We heard as we debated the rule that there have been some assurances given in a letter which none of us have seen from the majority leader to the Member that they're going to fix this, that they're going to fix it in conference. We're just asked to take a leap of faith. To me, that violates not only the promises that the Democratic majority made in this campaign to have an open, honest process with full disclosure, not back-room agreements. We don't even know what we're voting on. We're told, vote for something on blind faith. It'll be fixed. Yes, it's flawed. Yes, it won't work. Yes, we know we're not paying for it, but we'll do that later. Trust us.

You know, it's one thing to ask Members of Congress, it's another thing to ask the American people for their representatives to pass something they have no idea entirely what it is; to act on the assurance of a letter that 433 Members have not seen, surely not the 210 in the minority.

Policyholders are also shortchanged in this legislation. If an insurance company's losses exceed a certain level, the new bill that Members saw for the first time last night says that the consumer gets no more money until a later Congress acts, regardless of what the insurance policy says or what the company agreed to pay. In other words, they're writing a policy, the company is agreeing to pay a certain amount, but all of it is contingent upon Congress then coming in and paying for it. I'm not sure that's even constitutional, that we as a legislative body would say, go out and write insurance policies, tell policyholders this is their coverage, and another legislative body, 5, 10, 15 years down the road, they'll come in and they'll pay for it. How do we know that? What will the policy read? It will be interesting to see what the policy says. All this is contingent upon an act of Congress. How about all of this is contingent upon the ability of the United States to write such a check, or the willingness of the people to do that? What if these policies are extended and then we have a new Congress and that Congress says ''no''? The policyholders have paid for something and they have no assurance they'll ever receive a dime.

While I am a strong supporter of what has to this date been the approach of Congress for short-term extensions of this program that continues down the road of phasing out the government backstop, the taxpayer funding, and phases in greater private sector participation, and by private sector participation, I simply mean that those who are provided the coverage pay for the coverage, not someone in rural Kansas or New Mexico or Georgia, but that who's getting the benefit pays the price, not the American people.

I cannot support this bill. It extends the program for 15 years, in other words, more or less basically permanent. It writes a blank check, asks the taxpayers to pay it, but doesn't pay for it now. It makes no provisions for paying for it, other than a letter from the majority leader to a member of the New York delegation saying, in a month or two, we know this is a flawed bill, it's a no go, but we'll fix it. But vote for it right now. I cannot do that. I cannot ask the Members of the minority to do that.

Mr. Chairman, let me just say in closing that Members on this side of the aisle are prepared and we have been prepared to strongly support an extension of the TRIA program that is fiscally responsible, that does the right thing for taxpayers. But we're not going to vote for something we have no idea what we have, other than an assurance in a letter we have not seen.

While we have complete bipartisan agreement on the merits of the current TRIA program, we know that in the aftermath of 9/11 there was a need to act. We acted. We've been successful. Let's not change something that's proven to work well with a blank check from the taxpayers. This bill is a gimmick. It increases government subsidies without providing greater certainty in the marketplace. I urge my colleagues to oppose this legislation.

Mr. Chairman, I reserve the balance of my time.

Mr. FRANK of Massachusetts. Mr. Chairman, I yield myself first 30 seconds to note that I was impressed when the gentleman said he was going to vote against this bill because of this new amendment. But he voted against the bill the last time, so apparently my friend from Alabama intends to vote against this bill twice, because he voted against it in committee. So no one should think that the effort to deal with PAYGO is the reason he's voting against it.

Secondly, no one is asking anybody to accept any blank checks, and that is a misrepresentation of the legislative process. Changes will be made, I hope, in an open way. There will be an open conference, in total contrast to the way in which his party operated. I guarantee Members, as chairman of this committee, that we will have a conference committee, it will be a legitimate conference committee, and everything will be done openly, and votes will be taken. So no one is asking anybody to do anything in secret.

And again, the gentleman, having already voted against the bill, there are only so many bases you can claim on which you vote against the bill. He says he's not going to vote for the bill. We never thought he would. He voted against it the last time.

Mr. Chairman, I yield 5½ minutes to the gentleman from New York (Mr. ACKERMAN).

Mr. ACKERMAN. Mr. Chairman, on September 11, in addition to the enormous loss of human life, the value of which cannot be measured, our Nation suffered catastrophic economic losses. The attacks of September 11 resulted in $30 billion worth of insured losses, the largest catastrophic insurance loss in the history of the United States, larger than any blizzard, tornado or hurricane. As a result, insurers and reinsurers began to worry about the likelihood and the cost of a future terrorist attack.

Worrying about risk and then monetizing that risk is the key to the insurance industry, which is an essential element in a modern dynamic economy. As happened, businesses with legitimate concerns about their solvency, insurance and reinsurance firms withdrew from the market where the attack took place. As the supply of terrorism insurance rapidly decreased, New York City developers, for whom terrorism insurance was essential to secure financing for their projects, were put in a precarious position. They needed terrorism insurance to continue building, but the market for insurance simply did not have enough supply to meet their demand. Similar shortages began occurring throughout the country. In simple terms, there was a market failure.

It was out of this dilemma that the critical need to address that original version of TRIA was born. TRIA increased the availability of terrorism insurance coverage by creating a Federal backstop that would share the burden of losses caused by any future attacks of terrorism with the insurance industry.

In the wake of 9/11, we had hoped that a temporary, 3-year program would provide enough of a shield to allow the market to fully recover. By late 2005, however, the Financial Services Committee and others in Congress realized that TRIA had not resulted in as quick or as robust a recovery of the market as was originally hoped. TRIA was extended for an additional 2 years, and is currently set to expire on December 31 of this year.

Mr. Chairman, the Terrorism Risk Insurance Revision and Extension Act is a major achievement. It eliminates the distinction between foreign and domestic acts of terror. It incorporates group life insurance into the program. And, most importantly, this legislation extends TRIA for another 15 years.

Let us be clear: the enemy of business is uncertainty. This is particularly true for multi-million or multi-billion dollar real estate development projects, the kind that breathe life into our Nation. Designing, securing capital and then contracting for construction

is a multi-year process, and if we want these kinds of projects to go forward during these uncertain times, there is simply no alternative to providing a long-term terrorism insurance backstop.

Extending TRIA by 15 years is not a whim. It is not an arbitrary number. A 15-year extension would allow developers to secure 10- and 15-year bonds when financing their projects and would cover the life span of construction for our Nation's most innovative and remarkable development projects.

Equally as important to our Nation's developers, insurers and reinsurers is the inclusion of the so-called ''reset mechanism'' in this legislation. This language ensures that, in the aftermath of another catastrophic terrorist attack, the affected area or areas do not experience the same capacity problems that we experienced in New York following September 11.

To be clear, however, the reset mechanism included in H.R. 2761 is not a special favor extended to New York. Under the language I worked out with Mr. BAKER, representing the minority side, in the event of a terrorist attack with losses of $1 billion or greater, the deductibles for any insurance company that pays out losses due to the event immediately would lower to 5 percent, while the nationwide trigger for any insurer for any future event drops to $5 million.

Mr. BAKER and I also reached agreement on my proposal to enable the Secretary of the Treasury to aggregate the total losses for two or more attacks that occur in the same geographic area in the same year, if the Secretary so chooses, so that if the total insured losses for those events are over $1 billion, the reset mechanism would be triggered. Permitting the Secretary of the Treasury to aggregate the losses of two or more attacks in the same year is absolutely essential to protect our Nation's developers, insurers and reinsurers from a scenario in which the same area suffers a loss of $1 billion in insured losses, either from two or more medium-scale attacks or from one large-scale attack.

The reset language is a true bipartisan compromise with the minority, accommodating a vast number of their concerns, and one in which I think Members of both sides should be very pleased. The new language simultaneously addresses the need to boost capacity in our Nation's highest risk areas, while recognizing that in case America suffers another catastrophic terrorist attack anywhere in this Nation, capacity shortages could be expected not only in the geographic area surrounding the site of the attack but also, quite possibly, throughout the Nation as a whole.

The chairman has asserted that he would accommodate the needs of those who have complained about the openness of the process, which I assure everybody is open. And as the leader of the conference, when the House goes into conference on this matter, Mr. Chairman, could you give us your assurance that this bill will come back in the kind of form that we will not have an issue?

Mr. FRANK of Massachusetts. Absolutely.

Let me just say, first of all, having grown up in New Jersey, I'm used to complaints from New Yorkers. But in this particular case I believe they are entirely legitimate and justified, and I can assure the gentleman that we will work together in an open way to resolve it.

Mr. BACHUS. Mr. Chairman, I would yield the gentleman from New York 30 seconds to answer an inquiry if he would allow me.

I would ask the gentleman, this letter that we heard of earlier from Mr. HOYER to yourself, could you share a copy of that letter with the minority?

Mr. ACKERMAN. This is a private letter from the leadership to myself. I will be glad to show it to a Member of the minority side that signed the letter.

Mr. BACHUS. Could we see it now?

Mr. ACKERMAN. I will share it with a Member of the minority side who signed the letter.

Mr. BACHUS. Could we make a copy of it?

Mr. ACKERMAN. I think you have heard my answer.

Mr. BACHUS. So this is a private sort of agreement between the two of you?

Mr. ACKERMAN. This is the word of the majority leader to our delegation.

□ 1245

Mr. BACHUS. Mr. Chairman, at this time I yield 2 minutes to the gentleman from New Mexico (Mr. PEARCE).

Mr. PEARCE. Mr. Chairman, just as a disclaimer to the chairman of the committee, I did vote against this bill in committee and am still talking against the bill. Mr. Chairman, that is always a shock to you, and I'm just trying to settle your nerves down here at the beginning of my comments.

I am supportive of the TRIA concept in general. I understand the market is not yet where it needs to be. As I explained in committee, our company was one of the companies who had to renew our insurance 30 days after 9/11. On October 11 every year we had to renew insurance. So we were some of the first to encounter the problem that some insurances simply weren't going to write insurance if we did not have some solutions. So I understood the concept. But we put into place some legislative changes that were slowly moving the marketplace to where it needed to be.

And the market was responding. The marketplace was increasing the deductible percentages. The trigger limit was raised between the first two versions of the TRIA bill, and the industry retention level was raised, the Federal co-share was lowered, and those were all positive signs because we all recognized that the last thing we want to do is have, say, an agency like the Postal Service in charge of risk insurance. It does not meet the standards for a very mobile market.

So in the long term, we would like to have the private sector handling this problem. It's where the responsibility then would fall on the people who are getting the benefit.

As it is written, this bill begins to move us far beyond that concept. It begins to increase the mission, providing what should have been a temporary solution making it into a 15-year solution and with decreasing amounts of private sector employment or utilization. So responsibility in the end should be borne by the people who are buying the insurance and the insurance companies.

And, again, I would speak against the bill, and I thank the gentleman for yielding.

Mr. FRANK of Massachusetts. Mr. Chairman, I yield 2 minutes now to a senior member of our committee, the Chair of the Subcommittee on Financial Institutions and Consumer Credit, someone who has worked a great deal on this, the gentlewoman from New York (Mrs. MALONEY).

Mrs. MALONEY of New York. Mr. Chairman, I thank our chairman for his heroic leadership on this, along with the New York delegation, GARY ACKERMAN, and many, many others. This is an absolutely necessity for New York City and for our country and for our economy.

After 9/11, I have never seen this body so united and determined, and I thank you for all of your help. But by far, the most important action by this Congress was enacting TRIA. Before TRIA, we could not even build a Popsicle stand in lower Manhattan. No one could build anything. Critical to our economic recovery was the passage of this Federal backstop, and I implore my colleagues to join the leadership, Mr. FRANK and others, in passing this.

They say it is not needed, but I hear from businesses in New York they cannot get insurance. Some have gone to Lloyd's of London. They get insurance policies that say you have this policy on the condition that TRIA is reauthorized. This is critically important.

And I would like to stress to my colleagues that a very important part of our homeland security is our economic security. TRIA not only helped the rebuilding of New York City, it created jobs and helped America's economy grow despite the continuing terrorist threats against the United States.

TRIA has no cost to the taxpayer unless there is a terrorist attack. And in that terrible event, if it happens, and I hope it doesn't, TRIA saves the government money by structuring what would otherwise be hastily drafted emergency spending. Of course, setting up a public/private partnership to provide insurance coverage is more cost-effective than throwing money at the disaster after the fact.

So this is very important. I would like to be associated with the comments of my colleagues Mr. ACKERMAN and Mr. FRANK on the reset and the need for long-term planning, 15 years. I thank my colleagues for your help after 9/11. Give our economy help now. Vote for this.

Mr. BACHUS. Mr. Chairman, I yield 5 minutes to the gentleman from Texas (Mr. HENSARLING).

Mr. HENSARLING. Mr. Chairman, I thank the gentleman for yielding. I certainly thank him for his leadership in this area.

If I could paraphrase President Ronald Reagan, the closest thing to eternal life on Earth is a Federal program. And certainly the legislation that comes before us today helps prove this.

When TRIA was brought to the floor, and I, admittedly, was not here but I have read the RECORD, supposedly it was to be a temporary program at a time of great economic hardship to our Nation.

I just heard the gentlewoman from New York speak very eloquently on the subject. But I recall from the RECORD her own words: ''We are simply working to keep our economy on track with a short-term program that addresses the new terrorist threat.''

Now we are being asked for a 15-year extension on what has already been a 5-year program.

The gentleman from Pennsylvania, who is now our chairman of the Capital Markets Subcommittee: ''We wisely designed the TRIA Act as a temporary backstop to get our Nation through a period of economic uncertainty until the private sector could develop models.''

Now, maybe those on the other side of the aisle have a different definition of ''temporary.'' I was here to vote for the TRIA extension, and I voted for it. I thought that the market needed some time to develop. But let's face it. If we vote for this, we are voting for a permanent, a de facto permanent, huge government insurance program on top of those that we already have, none of which, none of which, are financially sound.

And we have to remember when we are hearing debate on the floor about how critical it is in the fight against terror that we have terrorism reinsurance. I believe terrorism reinsurance is important, but I think even more important in fighting terror is prevention, ensuring it doesn't happen in the first place. And yet we have Member after Member after Member on the other side of the aisle that would make it more difficult for our government to monitor the conversations of suspected terrorists. We have Member after Member on the other side of the aisle voting to assure that a portion of our intelligence budget, to paraphrase the former Director of the CIA, goes to spying on bugs and bunnies instead of terrorists. Prevention is what is key in the fight against this terror.

Now, of course, reinsurance is important, and, again, as I said, I voted for another extension. But to hear those on the other side of the aisle, they would say, well, there is no way that the market can develop this. I'm not sure I agree with that, and I know that the President's working group on financial markets doesn't agree with that. They say that the availability and affordability of terrorism risk insurance has improved since the terrorist attacks. Despite increases in risk retentions under TRIA, insurers have allocated additional capacity to terrorism risk, prices have declined, and take-up rates have increased.

And let me quote here from this working group: ''The presence of subsidized Federal reinsurance through TRIA appears to negatively affect the emergence of private reinsurance capacity because it dilutes demand for private sector reinsurance.''

Now, the chairman, whom I certainly respect, and he is entitled to his own opinions, he doesn't believe the market could ever develop. Well, I would respectfully say to our chairman: How are we ever going to know? How are we ever going to know when you are giving away something for free that the market otherwise would charge for and all of the signs are there that the market can develop?

Some tell us this is a new risk that we don't know how to model for. Well, there was a time when the insurance industry didn't know how to model for airline catasrophes. They didn't know how to model for data processing collapses. And this is not the first time in our Nation's history that we have faced great threats. How did we model the Cold War when thousands of nuclear arms were pointed at us and somehow construction still took place in America?

Construction has taken place in New York based upon a 3-year extension, not a de facto permanent extension, but based on a 3-year extension with higher deductibles and with less government subsidy.

So I don't believe that building is going to come to a complete stop. But if there is a market failure, we could have worked on a bipartisan basis for something restricted that was temporary, dealing with nuclear, chemical, and biological, with large deductibles and large industry retentions.

Instead, we are going to create a massive new insurance program that threatens the taxpayer, another great threat to this Nation. We should oppose this bill.

Mr. FRANK of Massachusetts. Mr. Chairman, I now yield 2 minutes to another member of the committee, whose district in Jersey City is as close to the site of the terrorism attack of 2001 as any, other than the district in which it happened.

Mr. SIRES. Mr. Chairman, I thank the chairman for yielding me time.

As you know, my district is in northern New Jersey, right across the river from New York City. I also represent parts of Newark and Jersey City, which are both considered high-threat areas. As a matter of fact, the New York Times has called parts of my district as containing two of the most dangerous miles in the country. As you can imagine, my constituents deal with the threat of terrorism every day.

When I was Speaker of the New Jersey Assembly, I made homeland security a top priority. Already in my first year in the U.S. House of Representatives, we have tackled important national security issues. The reauthorization of TRIA is another step in the process and something of great importance to the businesses of my congressional district and to this country.

I believe that the Financial Services Committee has thoroughly considered this reauthorization. We held hearings in New York City back in March where we had the opportunity to hear directly from the mayor of New York, Mayor Bloomberg, and Senator SCHUMER about the need for TRIA reauthorization. I am confident that H.R. 2761 takes their suggestions into consideration. The work of the Financial Services Committee that led to the drafting of this bill makes me proud to be a cosponsor. I think this legislation addresses all the major issues involved in the reauthorization, while maintaining the system that continues to ensure that there is coverage for terrorist attacks.

I want to thank Chairman FRANK and Congressman CAPUANO for introducing the reauthorization legislation, and I look forward to working with the committee and the leadership to make sure that this bill passes.

Mr. BACHUS. Mr. Chairman, I yield 3 minutes to the gentleman from Texas (Mr. CULBERSON).

Mr. CULBERSON. Mr. Chairman, this bill should be defeated because it is irresponsible and absolutely fiscally dangerous to pass a piece of legislation like this with an open-ended obligation on the U.S. Treasury. The bill should be defeated because, for all practical purposes, no private insurer will ever write coverage again in this area because they can now count on the U.S. Treasury to pay for this coverage. And the bill should be defeated because of its massive potential cost that the CBO has scored it, a 10-year cost of about $10.4 billion.

But I think probably the most important reason this bill should be defeated is one that we, as stewards of the Treasury, need to keep in mind on every bill, on every amendment, on every vote that involves spending a dollar of the taxpayers' money, that all of us in Congress should keep in mind the single, in my mind, most important fact that I have run across as a Member of Congress, and that is that David Walker, the Comptroller General of the United States, the director of the Government Accountability Office, has estimated that in order to pay off the existing obligations of the Federal Government, both direct and indirect, the existing obligations of the Federal

Government are so massive that every American would have to buy $170,000 worth of Treasury bills today in order to pay off the debt, the interest on the national debt, Medicare, Medicaid, Social Security. All the existing obligations, the Federal programs that are out there in existence today, those obligations are so massive that every living American would have to buy $170,000 in Treasury bills in order to pay them off.

□ 1300

It is absolutely imperative that this Congress on every bill, every amendment and every vote do everything we can to prevent adding to that burden, and to subtract from it as much as we can as, in our private lives, if you had a second mortgage on a house and the credit cards were all topped out, you would only spend money on the bare essentials. We have the same obligation, and even higher, a greater obligation here in Congress, as stewards of the Federal Treasury, to ensure that we're not passing on obligations to future generations, or adding to that $170,000 burden. And I don't want to hear the proponents of this bill come back and say, well, this administration added a lot to that burden. I can tell you personally I voted against almost every one of those big spending initiatives that the White House proposed. My district opposed a lot of the expansions of these big new spending programs. I voted against No Child Left Behind as a violation of the 10th amendment and spending money we didn't have. I voted against the Medicare prescription drug bill as spending money we didn't have. I voted against the farm bill as spending money we didn't have and I'm not going to pass that on to my daughter or future generations.

Most of us on this side, the fiscal conservatives in this House, have consistently opposed big new spending programs, and this bill is probably the worst I've seen so far. It is, in my mind, a perfect illustration of a liberal Democrat fiscal policy that they have passed an open-ended obligation onto future generations, a blank check on the U.S. Treasury. It's an utterly irresponsible and dangerous piece of legislation and it should be defeated.

Mr. FRANK of Massachusetts. Mr. Chairman, I will give myself 15 seconds to say I was waiting for the gentleman to tell me he voted against the war in Iraq. He talked about all these things he voted against. Added together and doubled, they don't add up to the war in Iraq, the continuing indefinite drain. Hundreds of billions of dollars have already gone, and they are committed to spending hundreds of billions more to make us worse off.

Mr. Chairman, I yield 1½ minutes to the gentleman from North Dakota (Mr. POMEROY).

Mr. POMEROY. I thank my friend, the chairman, for yielding.

I commend the last two speakers on the Republican side because they have at last made it clear what this debate is really about: Is there a Federal role for assisting the private sector in dealing with the management of the infinite risk of terror, or is there not?

I'm really surprised to hear in this debate how firmly my friends on the other side of the aisle cling to the notion that the market and the market alone can work this one out.

I used to be an insurance commissioner. What I know about insurance is that infinite risk cannot be priced, it cannot be underwritten, it cannot be reserved, it doesn't work. And that is why, right across the face of the insurance industry, we have heard as a body from the experts that they cannot make this coverage work private sector alone. They can whittle away at the edges basically by backing away from risk, coshares, enormous deductibles, the rest of it, but they have not told us they can make this market function.

But in the face of what reality holds forth, the minority is unmoved. They don't like government making business work. And so even in the face of a very uncertain construction sector, they would pull this coverage away.

Pass this bill.

Mr. BACHUS. Mr. Chairman, I would like to inquire as to the remaining time on our side.

The CHAIRMAN. The gentleman from Alabama has 8 minutes left; the gentleman from Massachusetts has 9¼ minutes left.

Mr. BACHUS. Mr. Chairman, at this time I would like to yield 3½ minutes to the gentleman from Louisiana (Mr. BAKER).

Mr. BAKER. I thank the gentleman for yielding and am appreciative of this time.

I wish to express my appreciation to committee leadership for attempting to address a most difficult subject matter. I have had some interest in this matter for a period of years, and understand the difficulty of crafting a remedy to which all Members may agree.

However, I have been troubled by the characterization that there would be Members, if voting ''no'' on this measure, would be ideologues voting for some unusual reason rather than in the Nation's best interests or in the Nation's recovery effort in the great city of New York.

It would be of note, I think, to the body to recall that it was November 29, 2001, at 4:37 p.m., in this august body when the House had a recorded vote 2 months after 9/11 on the adoption of the very first Terrorism Risk Insurance Program. You will find in the RECORD, which I have a copy of should it be needed for review, Mr. ACKERMAN, Mr. CLYBURN, Mr. CROWLEY, Mr. HINCHEY, Mr. HOYER, Mr. ISRAEL, Mr. KANJORSKI, Mrs. MALONEY, Mrs. MCCARTHY, Ms. PELOSI, Mr. SERRANO, Ms. SLAUGHTER, Mr. WEINER, Ms. WATERS, Ms. VELÁZQUEZ, Mr. MEEKS, Mr. MCNULTY, Mr. ENGEL, Mr. FRANK all found it appropriate and the right discharge of duty to vote ''no'' on the terrorism reinsurance proposal adopted two months after 9/11.

Now, I have no criticism to be made of those Members for taking that action. They did what they thought best for their constituents in that window of responsibility. I would merely point out that in the bills that we have passed on two occasions in this House under Republican leadership, we looked upon this responsibility as a loan to the industry to help them at a time of serious liquidity crisis to be able to withstand this assault, meet their financial obligations to the insureds, and move forward. But at such time as it was determined the crisis had passed, there was a mandatory obligation to repay the taxpayers of the United States the generosity that was extended in the form of a bridge loan and to give back to the taxpayers their generosity which enabled the industry to survive.

This bill does not require mandatory repayment of assistance. It is, in fact, a gift to the industry in a time of crisis, which is appropriate. But in the period of time in which the industry returns to profitability, is it wrong to say, ''Taxpayers, here's your money back. You helped us in a crisis, now it's time for us to repay your generosity''? I think that is a pivotal cornerstone of whatever we do going forward in assisting sectors of our economy which have untoward experiences that we cannot predict, where there is serious economic dislocation. But it is not right to give away the taxpayers' money without accountability.

For that reason alone, I suggest Members, who may choose to do so, could oppose this legislation and do so on a philosophical basis that is purely defensible. There are many other reasons why some may have concern.

Now, I will be quick to acknowledge that I worked with the gentleman from New York in addressing one serious flaw, and I appreciate the gentleman's willingness to extend that courtesy and fix that one significant difficulty with a legislative proposal. I am appreciative of that, and I look forward to working with him as they go forward through this process.

The bill today is flawed, and I would hope you would seriously consider a ''no'' vote.

Mr. FRANK of Massachusetts. I yield 15 seconds to the gentleman from New York to make a response.

Mr. ACKERMAN. I thank the chairman.

My name was cited, along with a list of other New Yorkers having opposed the original TRIA when it came to the floor. The reason we did so is not because of TRIA, it was because the minority side, the Republican side at the time, tried to use this as a vehicle to move tort reform and added all sorts of tort reform provisions to the TRIA bill, which we absolutely opposed because it was a politically motivated move and not because of TRIA.

Mr. FRANK of Massachusetts. I yield 3¾ minutes to the gentleman from

Pennsylvania, the chairman of the subcommittee who guided this bill through a very thoughtful bipartisan markup.

(Mr. KANJORSKI asked and was given permission to revise and extend his remarks.)

Mr. KANJORSKI. Mr. Chairman, I rise in support of H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act. Because the supply of terrorism reinsurance has not returned to its pre-September 11 levels, we must now act to extend TRIA before the law expires on December 31.

Terrorism insurance plays a critical role in protecting jobs and promoting our Nation's economic security. While this legislation may contain a few provisions that cause me concern, passage of this bill today will move the process forward. This extension makes several meaningful and necessary reforms to the program.

First, this bill eliminates the distinction between foreign and domestic acts of terrorism. Terrorism, regardless of its cause or perpetrator, aims to destabilize the government. We must protect against that risk.

Second, H.R. 2761 incorporates group life insurance as a covered line. The original TRIA did not include group life. I am pleased that this House, as it did in 2005, has decided to correct that oversight. We need to protect individuals, not just buildings they work in, by adding group life to TRIA.

Third, the bill improves protection against acts of nuclear, biological, chemical and radiological terrorism. This coverage properly represents the most significant reform of this extension effort.

We designed TRIA to protect the economic security of our Nation against terrorist threats. Congress, therefore, should address the possible threat of an attack by nuclear, biological, chemical or radiological means. Recognizing insurers' difficulty of modeling and pricing these events, this package limits the exposure of insurers on this risk, but allows the market to grow over time. H.R. 2761 further allows Treasury to exempt certain small insurers from this requirement. We need each of these prior modifications in order to sustain our Nation's economic recovery after a terrorist event.

This legislation is not about helping the insurance industry. The Terrorist Risk Insurance Program is about the continued availability and affordability of terrorism coverage and keeping America's markets strong.

That said, I do have some lingering concerns about some provisions in the product before us. When considering this legislation in the Financial Services Committee, I recognized the need for a longer extension period, but a 15-year extension is too long in my view.

Additionally, we should improve the bill's reset mechanism going forward. A reset mechanism can help both the area suffering an attack and the Nation to recover after a terrorist event. It can also help insurers to rebuild capacity. However, we ought to make sure that the size of the reset is in proportion to the size of the loss and to rebuild private capacity as quickly as possible.

In closing, Mr. Chairman, this is not a Democratic or a Republican issue. As I have previously said on this floor, it is an American issue, a business issue, an economic security issue.

I encourage my colleagues, including Mr. BAKER, to put your doubts aside and help us move this process forward so that over the next 110 days we can provide the coverage necessary to keep the American economy growing.

Mr. BAKER. Mr. Chairman, I yield 3 minutes to the gentleman from Wisconsin (Mr. RYAN).

Mr. RYAN of Wisconsin. I thank the gentleman for yielding.

Mr. Chairman, I rise in opposition to this. My friend from North Dakota said in the debate a minute ago that the minority doesn't want the government to help business. That was kind of an odd characterization. Here's what the minority wants: We want Congress to keep its word. And what do I mean when I say that? In the beginning of this Congress, Congress said that they were going to pay for things as they go. We were going to have this vaunted PAYGO rule that when we commit new spending, we will pay for it. We won't do deficit spending. What does this bill do? This bill thumbs its nose at the PAYGO system.

I think the best description of how this bill is not paid for was written in Congress Daily this morning, and I quote: ''The House will take up legislation today to renew the Federal Government's Terrorism Risk Insurance Program despite concerns that it violates PAYGO rules. CBO has ruled that the bill, which would reauthorize and expand the program for 15 years and cost the Federal government $3.7 billion over 5 years, $10.4 billion over a 10-year period. House leaders pulled the bill last week because it carried no offsets, but Democratic leaders found a way around the problem by requiring that if an attack occurred, Congress would have to vote again in a fast-track procedure to release the funds contained in the bill.'' Well, to do it justice, it's about $8.4 billion net cost, just to set the record straight for the minority.

What they're basically doing here is they're declaring this an emergency when an emergency hasn't even occurred yet. They're basically declaring this emergency spending, outside of the budget rules, not paid for, $8.4 billion, before an emergency has even occurred.

I've seen gimmicks in my day, Mr. Chairman, but this one takes the cake. This violates PAYGO. If it doesn't do it technically, it sure does it in spirit. So if we're going to say we're going to pay for legislation, then, by golly, let's pay for legislation. This doesn't do that. Not to mention the fact that this crowds out the private sector. Not to mention the fact that this tells all the insurers, go ahead and release this insurance, and if a terrorist attack occurs, we'll have some emergency legislation that pays for it after the fact. It's kind of like telling the homeowner, you don't have to pay premiums on your insurance until after your house has been burnt down, then pay your premiums and then we'll give you your payback. It doesn't work like that. That's not how insurance works. That's not how taxpayers pay their bills. That's not how Congress should operate. And, more importantly, that is not the rules that this Congress said it would operate under.

This violates those rules. If not technically, it sure does so in spirit. And I think when Congress says it's a new day, that we're going to pay for our spending, by golly, that's exactly what Congress ought to do, and that is not what this Congress is doing.

□ 1315

For this and many other reasons, Mr. Chairman, this legislation is flawed. It should be defeated. It encourages a crowding out of the private sector. And more importantly, it doesn't pay for the promises that are being committed here today. That is wrong. That violates the rhetoric and the principles that the majority has set out for itself.

Mr. Chairman, I urge a ''no'' vote.

Mr. FRANK of Massachusetts. I yield 2 minutes to the gentlewoman from Florida (Ms. WASSERMAN SCHULTZ).

Ms. WASSERMAN SCHULTZ. Mr. Chairman, I ask the gentleman to engage in a colloquy.

On the travel fairness language included in the bill, there are two provisions which I believe require additional work and which I hope the gentleman will be willing to work on with me as the bill progresses toward conference, the war exception and the impact on existing State laws.

The first is the exception allowing denial or limitation of coverage for people traveling to areas under intense armed conflict. The current language uses the term ''ongoing military conflict''; however, this term is not defined in statute or any other legislation. We must make sure the language reflects the most accurate description of the conflict areas in question and not unintentionally include areas that do not rise to the definition of war zone.

Secondly, on another point that I want to try to ask for the gentleman's assistance in conference is the issue of how this law will affect the States with similar laws. The current provision is silent on the issue of States with stronger travel fairness laws on the book, States such as Florida, Colorado, and Washington. As representatives of the Federal Government, Congress should not attempt to preempt State laws with Federal legislation when the State law provides greater protection. In other words, the Federal law should act as a floor, not as a ceiling, a base level of protection for the consumer.

I would appreciate the gentleman's willingness to work to address these two issues in the conference.

Mr. FRANK of Massachusetts. I agree with the gentlewoman on both points. First, there is nothing in this language, and I should say that this issue of preventing unfair denials of life insurance, she was the one who brought it up. She brought it up in the prior Congress. And now that we are in the majority, we are able to accommodate it.

I appreciate the fact that the gentlewoman worked with us as we worked with the life insurance companies. I believe we have an acceptable set of principles. She is right that this language does need a little bit more, I think, refinement on conflict. I think there's a conceptual agreement. I agree with her as to the need for definition.

As a preemption, that is very simple. I am a strong believer we should not be preempting unless we say so explicitly. There has been an excess of subtle preemption. By itself, this bill does not do that. Insurance has been primarily a State issue. This is a Federal statement, but it is not at all meant to be preemptive.

Ms. WASSERMAN SCHULTZ. I thank the gentleman and Mr. BACHUS both for their support.

Mr. BACHUS. Mr. Chairman, TRIA is working well as a temporary matter. The insurance market is beginning to fill out and, sadly, this is a step in the wrong direction.

Mr. Chairman, I yield back the balance of my time.

Mr. FRANK of Massachusetts. Before I yield to the gentleman from Vermont (Mr. WELCH), I would just point out that when we voted on this in committee before we had the PAYGO glitch, the vote on the Republican side was 19 opposed, 14 in favor, so it was hardly a one-sided partisan bill. It partly reflects the work that the gentleman from Pennsylvania (Mr. KANJORSKI) did in accommodating a lot of the concerns.

Mr. Chairman, I yield 2 minutes to the gentleman from Vermont.

Mr. WELCH of Vermont. May I engage in a colloquy with the gentleman from Massachusetts?

Mr. FRANK of Massachusetts. Yes.

Mr. WELCH of Vermont. Mr. Chairman, among other things, your bill balances the needs of smaller insurers and larger insurers. You have two provisions in there to try to help the small insurers play their part but not be overly burdened.

Mr. FRANK of Massachusetts. Get to the question.

Mr. WELCH of Vermont. The question is this: Our small insurers in Vermont that do business in a good and friendly way usually are in the range of $100 million. That is above your limit. The requirement that they will have to, in effect, indicate an insolvency risk threatens their rating which would adversely affect their business.

My question is, as you go forward, and as new information becomes available, my hope is that you and the committee would be willing to make what adjustments are feasible within the context of the overall goal.

Mr. FRANK of Massachusetts. If the gentleman would yield, he has pointed to a very important issue. We did try to make some accommodation with the small insurers, but I don't think we have finally done that. But I would say, you know, the notion that a bill that comes to the floor is not graven in stone shouldn't come as a surprise to people. We have a Senate. We have a genuine conference. It will be an open conference.

I should say I understand why some of my colleagues on the Republican side were somewhat puzzled at the notion that we might go to conference and, in an open way in conference, further amend the bill. They didn't believe in that. They didn't have any. So for them, that was all done in secret.

We will have an open conference to address these. And this is one of the issues. I do believe that it is legitimate. We will be meeting with, and the staffs will be meeting with, the smaller private insurers. To the extent possible consistent with the purpose of the bill, we will seek to improve on the accommodation.

Mr. WELCH of Vermont. I very much appreciate that.

Mr. FRANK of Massachusetts. Mr. Chairman, I yield the balance of my time to the gentleman from Rhode Island (Mr. LANGEVIN).

The CHAIRMAN. The gentleman from Rhode Island is recognized for 1¼ minutes.

Mr. LANGEVIN. I truly do thank the gentleman from Massachusetts for yielding and the minority for granting the unanimous consent request.

Mr. Chairman, I rise in strong support of the Terrorism Risk Insurance Revision and Extension Act of 2007. This critical bill reauthorizes the Federal Terrorism Insurance Program, which backs up private insurers in the event of a terrorist attack and extends the measure for 15 years. As chairman of the Homeland Security Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, I am certainly pleased that this bill would ensure coverage in the event of a nuclear, biological, chemical or radiological attack.

While no one wants to ever imagine that a nuclear, chemical, biological, radiological event could occur, the possibility is, unfortunately, a reality. Therefore, we must not only protect against this risk, but ensure that our Nation can recover financially if the unthinkable does happen.

This measure takes an important step forward by lowering the deductible from 20 percent to 3.5 percent for insurance coverage against NCBR attacks, and I am certainly proud to support this important measure.

Mr. Chairman, I want to thank Chairman FRANK for his leadership on this important issue.

The CHAIRMAN. All time for general debate has expired.

Pursuant to the rule, the amendment in the nature of a substitute printed in the bill, modified by the amendment printed in part A of House Report 110–333, is adopted. The bill, as amended, shall be considered as an original bill for the purpose of further amendment under the 5-minute rule and shall be considered read.

The text of the bill, as amended, is as follows:

H.R. 2761

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Terrorism Risk Insurance Revision and Extension Act of 2007''.

SEC. 2. TERMINATION OF PROGRAM.

Subsection (a) of section 108 of the Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) is amended by striking ''December 31, 2007'' and inserting ''December 31, 2022''.

SEC. 3. REVISION OF TERRORISM INSURANCE PROGRAM.

(a) IN GENERAL.—The Terrorism Risk Insurance Act of 2002 is amended—

(1) by striking sections 101, 102, and 103 and inserting the following new sections:

''SEC. 101. CONGRESSIONAL FINDINGS AND PURPOSE.

''(a) FINDINGS.—The Congress finds that—

''(1) the ability of businesses and individuals to obtain property and casualty insurance at reasonable and predictable prices, in order to spread the risk of both routine and catastrophic loss, is critical to economic growth, urban development, and the construction and maintenance of public and private housing, as well as to the promotion of United States exports and foreign trade in an increasingly interconnected world;

''(2) property and casualty insurance firms are important financial institutions, the products of which allow mutualization of risk and the efficient use of financial resources and enhance the ability of the economy to maintain stability, while responding to a variety of economic, political, environmental, and other risks with a minimum of disruption;

''(3) the ability of the insurance industry to cover the unprecedented financial risks presented by potential acts of terrorism in the United States can be a major factor in the recovery from terrorist attacks, while maintaining the stability of the economy;

''(4) widespread financial market uncertainties have arisen following the terrorist attacks of September 11, 2001, including the absence of information from which financial institutions can make statistically valid estimates of the probability and cost of future terrorist events, and therefore the size, funding, and allocation of the risk of loss caused by such acts of terrorism;

''(5) a decision by property and casualty insurers to deal with such uncertainties, either by terminating property and casualty coverage for losses arising from terrorist events, or by radically escalating premium coverage to compensate for risks of loss that are not readily predictable, could seriously hamper ongoing and planned construction, property acquisition, and other business projects, generate a dramatic increase in rents, and otherwise suppress economic activity;

''(6) the United States Government should coordinate with insurers to provide financial compensation to insured parties for losses from acts of terrorism, contributing to the stabilization of the United States economy in a time of national crisis, and periodically assess the ability of the financial services industry to develop the systems, mechanisms, products, and programs necessary to create a viable financial services market for private terrorism risk insurance that will

lessen the financial participation of the United States Government;

''(7) in addition to a terrorist attack on the United States using conventional means or weapons, there is and continues to be a potential threat of a terrorist attack involving the use of unconventional means or weapons, such as nuclear, biological, chemical, or radiological agents;

''(8) as nuclear, biological, chemical, or radiological acts of terrorism (known as NBCR terrorism) present a threat of loss of life, injury, disease, and property damage potentially unparalleled in scope and complexity by any prior event, natural or man-made, the Federal Government's responsibility in providing for and preserving national economic security calls for a strong Federal role in ensuring financial compensation and economic recovery in the event of such an attack;

''(9) a report issued by the Government Accountability Office in September 2006 concluded that 'any purely market-driven expansion of coverage' for NBCR terrorism risk is 'highly unlikely in the foreseeable future', and the September 2006 report from the President's Working Group on Financial Markets concluded that reinsurance for NBCR terrorist events is virtually unavailable and that '[g]iven the general reluctance of insurance companies to provide coverage for these types of risks, there may be little potential for future market development';

''(10) group life insurance companies are important financial institutions whose products make life insurance coverage affordable for millions of Americans and often serve as their only life insurance benefit;

''(11) the group life insurance industry, in the event of a severe act of terrorism, is vulnerable to insolvency because high concentrations of covered employees work in the same locations, because primary group life insurers do not exclude conventional and NBCR terrorism risks while most catastrophic reinsurance does exclude such terrorism risks, and because a large-scale loss of life would fall outside of actuarial expectations of death; and

''(12) the United States Government should provide temporary financial compensation to insured parties, contributing to the stabilization of the United States economy in a time of national crisis, while the financial services industry develops the systems, mechanisms, products, and programs necessary to create a viable financial services market for private terrorism risk insurance.

''(b) PURPOSE.—The purpose of this title is to establish a temporary Federal program that provides for a transparent system of shared public and private compensation for insured losses resulting from acts of terrorism, in order to—

''(1) protect consumers by addressing market disruptions and ensure the continued widespread availability and affordability of property and casualty insurance and group life insurance for all types of terrorism risk, including conventional terrorism risk and nuclear, biological, chemical, and radiological terrorism risk;

''(2) allow for a transitional period for the private markets to stabilize, resume pricing of such insurance, and build capacity to absorb any future losses, while preserving State insurance regulation and consumer protections (unless otherwise preempted by this Act); and

''(3) provide finite liability limits for terrorism insurance losses for insurers and the United States Government.

"SEC. 102. DEFINITIONS.

''In this title, the following definitions shall apply:

''(1) ACT OF TERRORISM.—

''(A) CERTIFICATION.—The term 'act of terrorism' means any act that is certified by the Secretary, in concurrence with the Secretary of State, the Secretary of Homeland Security, and the Attorney General of the United States—

''(i) to be an act of terrorism;

''(ii) to be a violent act or an act that is dangerous to—

''(I) human life;

''(II) property; or

''(III) infrastructure;

''(iii) to have resulted in damage within the United States, or outside of the United States in the case of—

''(I) an air carrier or vessel described in paragraph (9)(B); or

''(II) the premises of a United States mission; and

''(iv) to have been committed by an individual or individuals as part of an effort to coerce the civilian population of the United States or to influence the policy or affect the conduct of the United States Government by coercion.

''(B) LIMITATION.—No act shall be certified by the Secretary as an act of terrorism if—

''(i) the act is committed as part of the course of a war declared by the Congress, except that this clause shall not apply with respect to any coverage for workers' compensation; or

''(ii) property and casualty insurance and group life insurance losses resulting from the act, in the aggregate, do not exceed $5,000,000.

''(C) CERTIFICATION OF ACT OF NBCR TERRORISM.—Upon certification of an act of terrorism, the Secretary, in concurrence with the Secretary of State, the Secretary of Homeland Security, and the Attorney General of the United States, shall determine whether the act of terrorism meets the definition of NBCR terrorism in this section. If such determination is that the act does meet such definition, the Secretary shall further certify such act of terrorism as an act of NBCR terrorism.

''(D) DETERMINATIONS FINAL.—Any certification of, or determination not to certify, an act as an act of terrorism or as an act of NBCR terrorism under this paragraph shall be final, and shall not be subject to judicial review.

''(E) NONDELEGATION.—The Secretary may not delegate or designate to any other officer, employee, or person, any determination under this paragraph of whether, during the effective period of the Program, an act of terrorism, including an act of NBCR terrorism, has occurred.

''(F) COMPENSATION SUBJECT TO FURTHER CONGRESSIONAL ACTION.—Nothwithstanding any certification of an act under this paragraph as an act of terrorism or an act of NBCR terrorism, Federal compensation under the Program shall be subject to the provisions of section 103(h).

''(G) SUBMISSION OF CERTIFICATION UNDER THIS PARAGRAPH.—Upon any certification under subparagraph (A), the Secretary shall submit such certification to the Congress.''.

''(2) AFFILIATE.—The term 'affiliate' means, with respect to an insurer, any entity that controls, is controlled by, or is under common control with the insurer.

''(3) AMOUNT AT RISK.—The term 'amount at risk' means face amount less statutory policy reserves for group life insurance issued by any insurer for insurance against losses occurring at the locations described in subparagraph (A) of paragraph (9).

''(4) CONTROL.—An entity has 'control' over another entity, if—

''(A) the entity directly or indirectly or acting through 1 or more other persons owns, controls, or has power to vote 25 percent or more of any class of voting securities of the other entity;

''(B) the entity controls in any manner the election of a majority of the directors or trustees of the other entity; or

''(C) the Secretary determines, after notice and opportunity for hearing, that the entity directly or indirectly exercises a controlling influence over the management or policies of the other entity; except that for purposes of any proceeding under this subparagraph, there shall be a presumption that any entity which directly or indirectly owns, controls, or has power to vote less than 5 percent of any class of voting securities of another entity does not have control over that entity.

''(5) COVERED LINES.—The term 'covered lines' means property and casualty insurance and group life insurance, as defined in this section.

''(6) DIRECT EARNED PREMIUM.—The term 'direct earned premium' means a direct earned premium for property and casualty insurance issued by any insurer for insurance against losses occurring at the locations described in subparagraph (A) of paragraph (9).

''(7) EXCESS INSURED LOSS.—The term 'excess insured loss' means, with respect to a Program Year, any portion of the amount of insured losses during such Program Year that exceeds the cap on annual liability under section 103(e)(2)(A).

''(8) GROUP LIFE INSURANCE.—The term 'group life insurance' means an insurance contract that provides life insurance coverage, including term life insurance coverage, universal life insurance coverage, variable universal life insurance coverage, and accidental death coverage, or a combination thereof, for a number of individuals under a single contract, on the basis of a group selection of risks, but does not include 'Corporate Owned Life Insurance' or 'Business Owned Life Insurance,' each as defined under the Internal Revenue Code of 1986, or any similar product, or group life reinsurance or retrocessional reinsurance.

''(9) INSURED LOSS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'insured loss' means any loss resulting from an act of terrorism (including an act of war, in the case of workers' compensation) that is covered by primary or excess property and casualty insurance, or group life insurance to the extent of the amount at risk, issued by an insurer, if such loss—

''(i) occurs within the United States; or

''(ii) occurs to an air carrier (as defined in section 40102 of title 49, United States Code), to a United States flag vessel (or a vessel based principally in the United States, on which United States income tax is paid and whose insurance coverage is subject to regulation in the United States), regardless of where the loss occurs, or at the premises of any United States mission.

''(B) LIMITATION FOR GROUP LIFE INSURANCE.—Such term shall not include any losses of an insurer resulting from coverage of any single certificate holder under any group life insurance coverages of the insurer to the extent such losses are not compensated under the Program by reason of section 103(e)(1)(D).

''(10) INSURER.—The term 'insurer' means any entity, including any affiliate thereof—

''(A) that is—

''(i) licensed or admitted to engage in the business of providing primary or excess insurance, or group life insurance, in any State;

''(ii) not licensed or admitted as described in clause (i), if it is an eligible surplus line carrier listed on the Quarterly Listing of Alien Insurers of the NAIC, or any successor thereto;

''(iii) approved for the purpose of offering property and casualty insurance by a Federal agency in connection with maritime, energy, or aviation activity;

''(iv) a State residual market insurance entity or State workers' compensation fund; or

''(v) any other entity described in section 103(f), to the extent provided in the rules of the Secretary issued under section 103(f);

''(B) that receives direct earned premiums for any type of commercial property and casualty insurance coverage, or, in the case of group life insurance, that receives direct premiums, other than in the case of entities described in sections 103(d) and 103(f); and

''(C) that meets any other criteria that the Secretary may reasonably prescribe.

''(11) INSURER DEDUCTIBLE.—The term 'insurer deductible' means—

''(A) for the Transition Period, the value of an insurer's direct earned premiums over the calendar year immediately preceding the date of enactment of this Act, multiplied by 1 percent;

''(B) for Program Year 1, the value of an insurer's direct earned premiums over the calendar year immediately preceding Program Year 1, multiplied by 7 percent;

''(C) for Program Year 2, the value of an insurer's direct earned premiums over the calendar year immediately preceding Program Year 2, multiplied by 10 percent;

''(D) for Program Year 3, the value of an insurer's direct earned premiums over the calendar year immediately preceding Program Year 3, multiplied by 15 percent;

''(E) for Program Year 4, the value of an insurer's direct earned premiums over the calendar year immediately preceding Program Year 4, multiplied by 17.5 percent;

''(F) for Program Year 5, the value of an insurer's direct earned premiums over the calendar year immediately preceding Program Year 5, multiplied by 20 percent;

''(G) for each additional Program Year—

''(i) with respect to property and casualty insurance, the value of an insurer's direct earned premiums over the calendar year immediately preceding such Program Year, multiplied by 20 percent; and

''(ii) with respect to group life insurance, the value of an insurer's amount at risk over the calendar year immediately preceding such Program Year, multiplied by 0.0351 percent;

''(H) notwithstanding subparagraphs (A) through (G), for the Transition Period or any Program Year, if an insurer has not had a full year of operations during the calendar year immediately preceding such Period or Program Year, such portion of the direct earned premiums with respect to property and casualty insurance, and such portion of the amounts at risk with respect to group life insurance, of the insurer as the Secretary determines appropriate, subject to appropriate methodologies established by the Secretary for measuring such direct earned premiums and amounts at risk;

''(I) notwithstanding subparagraphs (A) through (H) and (J), in the case of any act of NBCR terrorism, for any additional Program Year—

''(i) with respect to property and casualty insurance, the value of an insurer's direct earned premiums over the calendar year immediately preceding such Program Year, multiplied by a percentage, which—

''(I) for the second additional Program Year, shall be 3.5 percent; and

''(II) for each succeeding Program Year thereafter, shall be 50 basis points greater than the percentage applicable to the preceding additional Program Year; and

''(ii) with respect to group life insurance, the value of an insurer's amount at risk over the calendar year immediately preceding such Program Year, multiplied by a percentage, which—

''(I) for the first additional Program Year, shall be 0.00614 percent; and

''(II) for each succeeding Program Year thereafter, shall be 0.088 basis point greater than the percentage applicable to the preceding additional Program Year; and

''(J) notwithstanding subparagraph (G)(i), if aggregate industry insured losses resulting from a certified act of terrorism exceed $1,000,000,000, for any insurer that sustains insured losses resulting from such act of terrorism, the value of such insurer's direct earned premiums over the calendar year immediately preceding the Program Year, multiplied by a percentage, which—

''(i) for the first additional Program Year shall be 5 percent;

''(ii) for each additional Program Year thereafter, shall be 50 basis points greater than the percentage applicable to the preceding additional Program Year, except that if an act of terrorism occurs during any additional Program Year that results in aggregate industry insured losses exceeding $1,000,000,000, the percentage for the succeeding additional Program Year shall be 5 percent and the increase under this clause shall apply to additional Program Years thereafter;

except that for purposes of determining under this subparagraph whether aggregate industry insured losses exceed $1,000,000,000, the Secretary may combine insured losses resulting from two or more certified acts of terrorism occurring during such Program Year in the same geographic area (with such area determined by the Secretary), in which case such insurer shall be permitted to combine insured losses resulting from such acts of terrorism for purposes of satisfying its insurer deductible under this subparagraph; and except that the insurer deductible under this subparagraph shall apply only with respect to compensation of insured losses resulting from such certified act, or combined certified acts, and that for purposes of compensation of any other insured losses occurring in the same Program Year, the insurer deductible determined under subparagraph (G)(i) or (I) shall apply.

''(12) NAIC.—The term 'NAIC' means the National Association of Insurance Commissioners.

''(13) NBCR TERRORISM.—The term 'NBCR terrorism' means an act of terrorism that involves nuclear, biological, chemical, or radiological reactions, releases, or contaminations, to the extent any insured losses result from any such reactions, releases, or contaminations.

''(14) PERSON.—The term 'person' means any individual, business or nonprofit entity (including those organized in the form of a partnership, limited liability company, corporation, or association), trust or estate, or a State or political subdivision of a State or other governmental unit.

''(15) PROGRAM.—The term 'Program' means the Terrorism Insurance Program established by this title.

''(16) PROGRAM YEARS.—

''(A) TRANSITION PERIOD.—The term 'Transition Period' means the period beginning on the date of enactment of this Act and ending on December 31, 2002.

''(B) PROGRAM YEAR 1.—The term 'Program Year 1' means the period beginning on January 1, 2003 and ending on December 31, 2003.

''(C) PROGRAM YEAR 2.—The term 'Program Year 2' means the period beginning on January 1, 2004 and ending on December 31, 2004.

''(D) PROGRAM YEAR 3.—The term 'Program Year 3' means the period beginning on January 1, 2005 and ending on December 31, 2005.

''(E) PROGRAM YEAR 4.—The term 'Program Year 4' means the period beginning on January 1, 2006 and ending on December 31, 2006.

''(F) PROGRAM YEAR 5.—The term 'Program Year 5' means the period beginning on January 1, 2007 and ending on December 31, 2007.

''(G) ADDITIONAL PROGRAM YEAR.—The term 'additional Program Year' means any additional one-year period after Program Year 5 during which the Program is in effect, which period shall begin on January 1 and end on December 31 of the same calendar year.

''(17) PROPERTY AND CASUALTY INSURANCE.—The term 'property and casualty insurance'—

''(A) means commercial lines of property and casualty insurance, including excess insurance, workers' compensation insurance, and directors and officers liability insurance; and

''(B) does not include—

''(i) Federal crop insurance issued or reinsured under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.), or any other type of crop or livestock insurance that is privately issued or reinsured;

''(ii) private mortgage insurance (as that term is defined in section 2 of the Homeowners Protection Act of 1998 (12 U.S.C. 4901)) or title insurance;

''(iii) financial guaranty insurance issued by monoline financial guaranty insurance corporations;

''(iv) insurance for medical malpractice;

''(v) health or life insurance, including group life insurance;

''(vi) flood insurance provided under the National Flood Insurance Act of 1968 (42 U.S.C. 4001 et seq.);

''(vii) reinsurance or retrocessional reinsurance;

''(viii) commercial automobile insurance;

''(ix) burglary and theft insurance;

''(x) surety insurance; or

''(xi) professional liability insurance.

''(18) SECRETARY.—The term 'Secretary' means the Secretary of the Treasury.

''(19) STATE.—The term 'State' means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, each of the United States Virgin Islands, and any territory or possession of the United States.

''(20) UNITED STATES.—The term 'United States' means the several States, and includes the territorial sea and the continental shelf of the United States, as those terms are defined in the Violent Crime Control and Law Enforcement Act of 1994 (18 U.S.C. 2280, 2281).

''(21) RULE OF CONSTRUCTION FOR DATES.—With respect to any reference to a date in this title, such day shall be construed—

''(A) to begin at 12:01 a.m. on that date; and

''(B) to end at midnight on that date.

''SEC. 103. TERRORISM INSURANCE PROGRAM.

''(a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—There is established in the Department of the Treasury the Terrorism Insurance Program.

''(2) AUTHORITY OF THE SECRETARY.—Notwithstanding any other provision of State or Federal law, the Secretary shall administer the Program, and, subject only to subsection (h)(1), shall pay the Federal share of compensation for insured losses in accordance with subsection (e).

''(3) MANDATORY PARTICIPATION.—Each entity that meets the definition of an insurer under this title shall participate in the Program.

''(4) NBCR EXEMPTION FOR CERTAIN INSURERS.—Notwithstanding the requirements of paragraph (3):

''(A) ELIGIBILITY.—Upon request, the Secretary may provide an exemption from the requirements of subparagraph (B) of subsection (c)(1) in the Program to an entity that otherwise meets the definition of an insurer under this title if—

''(i) such insurer's direct earned premium is less than $50,000,000 in the calendar year immediately preceding the current additional Program Year; and

''(ii) the Secretary makes the determination set forth in subparagraph (D).

''(B) INSURER GROUP.—For purposes of subparagraph (A)(i), the direct earned premium of any insurer shall include the direct earned premiums of every affiliate of that insurer.

''(C) INFORMATION AND CONSULTATION.—Any insurer requesting an exemption pursuant to this paragraph shall provide any information the Secretary may require to establish its eligibility for the exemption. In developing standards for evaluating eligibility for the exemption under this paragraph, the Secretary shall consult with the NAIC.

''(D) DETERMINATION.—In making any determination regarding eligibility for exemption under this paragraph, the Secretary shall consult with the insurance commissioner of the State or other appropriate State regulatory authority where the insurer is domiciled and determine whether the insurer has demonstrated that it would become insolvent if it were required, in the event of an act of NBCR terrorism, to satisfy—

''(i) its deductible and maximum applicable share above the deductible pursuant to sections 102(11)(I) and 103(e)(1)(B), respectively, for such act of NBCR terrorism resulting in aggregate industry insured losses above the trigger established in section 103(e)(1)(C); or

''(ii) its maximum payment obligations for insured losses for such act of NBCR terrorism resulting in aggregate industry insured losses below the trigger established in section 103(e)(1)(C).

''(E) WORKERS' COMPENSATION AND OTHER COMPULSORY INSURANCE LAW.—In granting an exemption under this paragraph, the Secretary shall not approve any request for exemption with regard to State workers' compensation insurance or other compulsory insurance law requiring coverage of the risks described in subparagraph (B) of subsection (c)(1).

''(F) EXEMPTION PERIOD.—

''(i) IN GENERAL.—Any exemption granted to an insurer by the Secretary under this paragraph shall have a duration of not longer than 2 years.

''(ii) EXTENSION.—Notwithstanding clause (i), the Secretary may, upon application by an insurer granted an exemption under this paragraph, extend such exemption for additional periods of not longer than 2 years.

''(b) CONDITIONS FOR FEDERAL PAYMENTS.—No payment may be made by the Secretary under this section with respect to an insured loss that is covered by an insurer, unless—

''(1) there is enacted a joint resolution for payment of Federal compensation with respect to the act of terroism that resulted in the insured loss;

''(2) the person that suffers the insured loss, or a person acting on behalf of that person, files a claim with the insurer;

''(3) the insurer provides clear and conspicuous disclosure to the policyholder of the premium charged for insured losses covered by the Program (including the additional premium, if any, charged for the coverage for insured losses resulting from acts of NBCR terrorism as made available pursuant to subsection (c)(1)(B)) and the Federal share of compensation for insured losses under the Program—

''(A) in the case of any policy that is issued before the date of enactment of this Act, not later than 90 days after that date of enactment;

''(B) in the case of any policy that is issued within 90 days of the date of enactment of this Act, at the time of offer, purchase, and renewal of the policy; and

''(C) in the case of any policy that is issued more than 90 days after the date of enactment of this Act, on a separate line item in the policy, at the time of offer, purchase, and renewal of the policy;

''(4) the insurer processes the claim for the insured loss in accordance with appropriate business practices, and any reasonable procedures that the Secretary may prescribe; and

''(5) the insurer submits to the Secretary, in accordance with such reasonable procedures as the Secretary may establish—

''(A) a claim for payment of the Federal share of compensation for insured losses under the Program;

''(B) written certification—

''(i) of the underlying claim; and

''(ii) of all payments made for insured losses; and

''(C) certification of its compliance with the provisions of this subsection.

''(c) MANDATORY AVAILABILITY.—

''(1) AVAILABILITY OF COVERAGE FOR INSURED LOSSES.—Subject to paragraph (3), during each Program Year, each entity that meets the definition of an insurer under section 102 shall make available—

''(A) in all of its insurance policies for covered lines, coverage for insured losses that does not differ materially from the terms, amounts, and other coverage limitations applicable to losses arising from events other than acts of terrorism; and

''(B) in insurance policies for covered lines for which the coverage described in subparagraph (A) is provided, exceptions to the pollution and nuclear hazard exclusions of such policies that render such exclusions inapplicable only as to insured losses arising from acts of NBCR terrorism.

''(2) ALLOWABLE EXCLUSIONS IN OTHER COVERAGE.—Subject to paragraph (3) and notwithstanding any other provision of Federal or State law, including any State workers' compensation and other compulsory insurance law, if a person elects not to purchase an insurance policy with the coverage described in paragraph (1)—

''(A) an insurer may exclude coverage for all losses from acts of terrorism including acts of NBCR terrorism, except for State workers' compensation and other compulsory insurance law requiring coverage of the risks described in subsection (c)(1) (unless permitted by State law); or

''(B) an insurer may offer other options for coverage that differ materially from the terms, amounts, and other coverage limitations applicable to losses arising from events other than acts of terrorism;

except that nothing in this paragraph shall affect paragraph (4).

''(3) APPLICABILITY FOR NBCR TERRORISM.—Notwithstanding any other provision of this Act, paragraphs (1)(B) and (2) shall apply, beginning upon January 1, 2009, with respect to coverage for acts of NBCR terrorism, that is purchased or renewed on or after such date.

''(4) AVAILABILITY OF LIFE INSURANCE WITHOUT REGARD TO LAWFUL FOREIGN TRAVEL.—During each Program Year, each entity that meets the definition of an insurer under section 102 shall make available, in all of its life insurance policies issued after the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007 under which the insured person is a citizen of the United States or an alien lawfully admitted for permanent residence in the United States, coverage that neither considers past, nor precludes future, lawful foreign travel by the person insured, and shall not decline such coverage based on past or future, lawful foreign travel by the person insured or charge a premium for such coverage that is excessive and not based on a good faith actuarial analysis, except that an insurer may decline or, upon inception or renewal of a policy, limit the amount of coverage provided under any life insurance policy based on plans to engage in future lawful foreign travel to occur within 12 months of such inception or renewal of the policy but only if, at time of application—

''(A) such declination is based on, or such limitation applies only with respect to, travel to a foreign destination—

''(i) for which the Director of the Centers for Disease Control and Prevention of the Department of Health and Human Services has issued a highest level alert or warning, including a recommendation against non-essential travel, due to a serious health-related condition;

''(ii) in which there is an ongoing military conflict involving the armed forces of a sovereign nation other than the nation to which the insured person is traveling; or

''(iii)(I) that the insurer has specifically designated in the terms of the life insurance policy at the inception of the policy or at renewal, as applicable; and

''(II) with respect to which the insurer has made a good-faith determination that—

''(aa) a serious unlawful situation exists which is ongoing; and

''(bb) the credibility of information by which the insurer can verify the death of the insured person is compromised; and

''(B) in the case of any limitation of coverage, such limitation is specifically stated in the terms of the life insurance policy at the inception of the policy or at renewal, as applicable.

''(d) STATE RESIDUAL MARKET INSURANCE ENTITIES.—

''(1) IN GENERAL.—The Secretary shall issue regulations, as soon as practicable after the date of enactment of this Act, that apply the provisions of this title to State residual market insurance entities and State workers' compensation funds.

''(2) TREATMENT OF CERTAIN ENTITIES.—For purposes of the regulations issued pursuant to paragraph (1)—

''(A) a State residual market insurance entity that does not share its profits and losses with private sector insurers shall be treated as a separate insurer; and

''(B) a State residual market insurance entity that shares its profits and losses with private sector insurers shall not be treated as a separate insurer, and shall report to each private sector insurance participant its share of the insured losses of the entity, which shall be included in each private sector insurer's insured losses.

''(3) TREATMENT OF PARTICIPATION IN CERTAIN ENTITIES.—Any insurer that participates in sharing profits and losses of a State residual market insurance entity shall include in its calculations of premiums any premiums distributed to the insurer by the State residual market insurance entity.

''(e) INSURED LOSS SHARED COMPENSATION.—

''(1) FEDERAL SHARE.—

''(A) CONVENTIONAL TERRORISM.—Except as provided in subparagraph (B), the Federal share of compensation under the Program to be paid by the Secretary subject to subsection (h)(1), for insured losses of an insurer during any additional Program Year shall be equal to the sum of—

''(i) 85 percent of that portion of the amount of such insured losses that—

''(I) exceeds the applicable insurer deductible required to be paid during such Program Year; and

''(II) based upon pro rata determinations pursuant to paragraph (2)(B), does not result in aggregate industry insured losses during such Program Year exceeding $100,000,000,000; and

''(ii) 100 percent of the insured losses of the insurer that, based upon pro rata determinations pursuant to paragraph (2)(B), result in aggregate industry insured losses during such Program Year exceeding $100,000,000,000, up to the limit under paragraph (2)(A).

''(B) NBCR TERRORISM.—

''(i) AMOUNT OF COMPENSATION.—The Federal share of compensation under the Program to be paid by the Secretary for insured losses of an insurer resulting from NBCR terrorism during any additional Program Year shall be equal to the sum of—

''(I) the amount of qualified NBCR losses (as such term is defined in clause (ii)) of the insurer, multiplied by a percentage based on the aggregate industry qualified NBCR losses for the Program Year, which percentage shall be—

''(aa) 85 percent of such aggregate industry qualified NBCR losses of less than $10,000,000,000;

''(bb) 87.5 percent of such aggregate industry qualified NBCR losses between $10,000,000,000 and $20,000,000,000;

''(cc) 90 percent of such aggregate industry qualified NBCR losses between $20,000,000,000 and $40,000,000,000;

''(dd) 92.5 percent of such aggregate industry qualified NBCR losses of between $40,000,000,000 and $60,000,000,000; and

''(ee) 95 percent of such aggregate industry qualified NBCR losses of more than $60,000,000,000;

and shall be prorated per insurer based on each insurer's percentage of the aggregate industry qualified NBCR losses for such additional Program Year; and

''(II) 100 percent of the insured losses of the insurer resulting from NBCR terrorism that, based upon pro rata determinations pursuant to paragraph (2)(B), result in aggregate industry insured losses during such Program Year exceeding $100,000,000,000, up to the limit under paragraph (2)(A).

''(ii) QUALIFIED NBCR LOSSES.—For purposes of this subparagraph, the term 'qualified NBCR losses' means, with respect to insured losses of an insurer resulting from NBCR terrorism during an additional Program Year, that portion of the amount of such insured losses that—

''(I) exceeds the applicable insurer deductible required to be paid during such Program Year; and

''(II) based upon pro rata determinations pursuant to paragraph (2)(B), does not result in aggregate industry insured losses during such Program Year exceeding $100,000,000,000.

''(C) PROGRAM TRIGGER.—In the case of a certified act of terrorism occurring after March 31, 2006, no compensation shall be paid, pursuant to subsection (h)(1), by the Secretary under subsection (a), unless the aggregate industry insured losses resulting from such certified act of terrorism exceed $50,000,000, except that if a certified act of terrorism occurs for which resulting aggregate industry insured losses exceed $1,000,000,000, the applicable amount for any subsequent certified act of terrorism shall be the amount specified in section 102(1)(B)(ii).

''(D) LIMITATION ON COMPENSATION FOR GROUP LIFE INSURANCE.—Notwithstanding any other provision of this Act, the Federal share of compensation under the Program paid, pursuant to subsection (h)(1), by the Secretary for insured losses of an insurer resulting from coverage of any single certificate holder under any group life insurance coverages of the insurer may not during any additional Program Year exceed $1,000,000.

''(E) PROHIBITION ON DUPLICATIVE COMPENSATION.—The Federal share of compensation for insured losses under the Program shall be reduced by the amount of compensation provided by the Federal Government to any person under any other Federal program for those insured losses.

''(2) CAP ON ANNUAL LIABILITY.—

''(A) IN GENERAL.—Notwithstanding paragraph (1) or any other provision of Federal or State law, including any State workers' compensation or other compulsory insurance law, if the aggregate amount of the Federal share of compensation to be paid to all insurers pursuant to paragraph (1) exceeds $100,000,000,000, during any additional Program Year (until such time as the Congress may act otherwise with respect to such losses)—

''(i) the Secretary shall not make any payment under this title for any portion of the amount of the aggregate insured losses during such Program Year for which the Federal share exceeds $100,000,000,000; and

''(ii) no insurer that has met its insurer deductible shall be liable for the payment of any portion of the aggregate insured losses during such Program Year that exceeds $100,000,000,000.

''(B) INSURER SHARE.—For purposes of subparagraph (A), the Secretary shall determine the pro rata share of insured losses to be paid by each insurer that incurs insured losses under the Program.

''(C) CLAIMS ALLOCATIONS.—The Secretary shall, by regulation, provide for insurers to allocate claims payments for insured losses under applicable insurance policies in any case described in subparagraph (A). Such regulations shall include provisions for payment, for the purpose of addressing emergency needs of applicable individuals affected by an act of terrorism, of a portion of claims for insured losses promptly upon filing of such claims.

''(3) LIMITATION ON INSURER FINANCIAL RESPONSIBILITY.—

''(A) LIMITATION.—Notwithstanding any other provision of Federal or State law, including any State workers' compensation or other compulsory insurance law, an insurer's financial responsibility for insured losses from acts of terrorism shall be limited as follows:

''(i) FEDERAL COMPENSATION NOT PROVIDED.—In any case of an act of terrorism with respect to which there has not been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2), an insurer's financial responsbility for insured losses from such act of terrorism shall be limited to its applicable insurer deductible.

''(ii) FEDERAL COMPENSATION PROVIDED.—In any case of an act of terrorism with respect to which there has been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2), an insurer's financial responsbility for insured losses from such act of terrorism shall be limited to—

''(I) its applicable insurer deductible; and

''(II) its applicable share of insured losses that exceed its applicable insurer deductible, subject to the requirements of paragraph (2).

''(B) FEDERAL REIMBURSEMENT.—''In the case of any act of terrorism with respect to which there has been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2) and notwithstanding any other provision of Federal or State law, the Secretary shall—

''(i) reimburse insurers for any payment of excess insured losses made prior to publication of any notification pursuant to paragraph (4)(A);

''(ii) reimburse insurers for any payment of excess insured losses occurring on or after the date of any notification pursuant to paragraph (4)(A), but only to the extent that—

''(I) such payment is ordered by a court pursuant to subparagraph (C) of this paragraph or is directed by State law, notwithstanding this paragraph, or by Federal law;

''(II) such payment is limited to compensating insurers for their payment of excess insured losses and does not include punitive damages, or litigation or other costs; and

''(III) the insurer has made a good-faith effort to defend against any claims for such payment; and

''(iii) have the right to intervene in any legal proceedings relating to such claims specified in clause (ii)(III).

''(C) FEDERAL COURT JURISDICTION.—

''(i) CONDITIONS.—All claims relating to or arising out of an insurer's financial responsibility for insured losses from acts of terrorism under this paragraph shall be within the original and exclusive jurisdiction of the district courts of the United States, in accordance with the procedures established in subparagraph (D), if the Secretary certifies that the following conditions have been met, or that there is a reasonable likelihood that the following conditions may be met:

''(I) The aggregate amount of the Federal share of compensation to be paid to all insurers pursuant to paragraph (1) exceeds $100,000,000,000, pursuant to paragraph (2); and

''(II) the insurer has paid its applicable insurer deductible and its pro rata share of insured losses determined pursuant to paragraph (2)(B).

''(ii) REMOVAL OF STATE COURT ACTIONS.—If the Secretary certifies that conditions set forth in subclauses (I) and (II) of clause (i) have been met, all pending State court actions that relate to or arise out of an insurer's financial responsibility for insured losses from acts of terrorism under this paragraph shall be removed to a district court of the United States in accordance with subparagraph (D).

''(D) VENUE.—For each certification made by the Secretary pursuant to subparagraph (C)(i), not later than 90 days after the Secretary's determination the Judicial Panel on Multidistrict Litigation shall designate one district court or, if necessary, multiple district courts of the United States that shall have original and exclusive jurisdiction over all actions for any claim relating to or arising out of an insurer's financial responsibility for insured losses from acts of terrorism under this paragraph.

''(E) FEDERAL COURT JURISDICTION AND VENUE IN CASES OF NO FEDERAL COMPENSATION.—In the case of any act of terrorism with respect to which there has not been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2)—

''(i) all claims relating to or arising out of an insurer's financial responsbility for insured losses from such act of terrorism shall be within the original and exclusive jurisdiction of the district courts of the United States, in accordance with the procedures established in clause (iii);

''(ii) all pending State court actions that relate to or arise out of an insurer's financial responsbility for insured losses from such act of terrorism shall be removed to a district court of the United States in accordance with clause (iii); and

''(iii) not later than 90 days after the Secretary's certification of such act of terrorism, the Judicial Panel on Multidistrict Litigation shall designate one district court or, if necessary, multiple district courts of the United States that shall have original and exclusive jurisdiction over all actions for any claim relating to or arising out of an insurer's financial responsibility for insured losses from such act of terrorism.

''(4) NOTICES REGARDING LOSSES AND ANNUAL LIABILITY CAP.—

''(A) APPROACHING CAP.—If the Secretary determines estimated or actual aggregate Federal compensation to be paid pursuant to paragraph (1) equals or exceeds $80,000,000,000 during any Program Year, the Secretary shall promptly provide notification in accordance with subparagraph (D)—

''(i) of such estimated or actual aggregate Federal compensation to be paid;

''(ii) of the likelihood that such aggregate Federal compensation to be paid for such Program Year will equal or exceed $100,000,000,000; and

''(iii) that, pursuant to paragraph (2)(A)(ii), insurers are not required to make payments of excess insured losses.

''(B) EVENT LIKELY TO CAUSE LOSSES TO EXCEED CAP.—If any act of terrorism occurs that the Secretary determines is likely to cause estimated or actual aggregate Federal compensation to be paid pursuant to paragraph (1) to exceed $100,000,000,000 during any Program Year, the Secretary shall, not later than 10 days after such act, provide notification in accordance with subparagraph (D)—

''(i) of such estimated or actual aggregate Federal compensation to be paid; and

''(ii) that, pursuant to paragraph (2)(A)(ii), insurers are not required to make payments for excess insured losses.

''(C) EXCEEDING CAP.—If the Secretary determines estimated or actual aggregate Federal compensation to be paid pursuant to paragraph (1) equals or exceeds $100,000,000,000 during any Program Year—

''(i) the Secretary shall promptly provide notification in accordance with subparagraph (D)—

''(I) of such estimated or actual aggregate Federal compensation to be paid; and

''(II) that, pursuant to paragraph (2)(A)(ii), insurers are not required to make payments for excess insured losses unless the Congress provides for payments for excess insured losses pursuant to clause (ii) of this subparagraph; and

''(ii) the Congress shall determine the procedures for and the source of any payments for such excess insured losses.

''(D) PARTIES NOTIFIED.—Notification is provided in accordance with this subparagraph only if notification is provided—

''(i) to the Congress, in writing; and

''(ii) to insurers, by causing such notice to be published in the Federal Register.

''(E) DETERMINATIONS.—The Secretary shall make determinations regarding estimated and actual aggregate Federal compensation to be paid promptly after any act of terrorism as may be necessary to comply with this paragraph.

''(F) MANDATORY DISCLOSURE FOR INSURANCE CONTRACTS.—All policies for property and casualty insurance and group life insurance shall be deemed to contain a provision to the effect that, in the case of any act of terrorism with respect to which there has been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2), no insurer that has met its applicable insurer deductible and its applicable share of insured losses that exceed its applicable insurer deductible but are not compensated pursuant to paragraph (1), shall be obligated to pay for any portion of excess insured loss. Notwithstanding the preceding sentence, insurers shall include a disclosure in their policies detailing the maximum level of Government

assistance and the applicable insurer share. ''All policies for property and casualty insurance and group life insurance shall be deemed to contain, and insurers shall be permitted to include in their policies, a provision to the effect that, in the case of insured losses resulting from any act of terrorism with respect to which there has not been enacted a joint resolution for payment of Federal compensation described in subsection (h)(2), no insurer shall be obligated to pay for any portion of any such insured losses that exceeds its applicable insurer deductible.

''(5) FINAL NETTING.—The Secretary shall have sole discretion to determine the time at which claims relating to any insured loss or act of terrorism shall become final.

''(6) DETERMINATIONS FINAL.—Any determination of the Secretary under this subsection shall be final, unless expressly provided, and shall not be subject to judicial review.

''(7) INSURANCE MARKETPLACE AGGREGATE RETENTION AMOUNT.—For purposes of paragraph (8), the insurance marketplace aggregate retention amount shall be—

''(A) for the period beginning on the first day of the Transition Period and ending on the last day of Program Year 1, the lesser of—

''(i) $10,000,000,000; and

''(ii) the aggregate amount, for all insurers, of insured losses during such period;

''(B) for Program Year 2, the lesser of—

''(i) $12,500,000,000; and

''(ii) the aggregate amount, for all insurers, of insured losses during such Program Year;

''(C) for Program Year 3, the lesser of—

''(i) $15,000,000,000; and

''(ii) the aggregate amount, for all insurers, of insured losses during such Program Year;

''(D) for Program Year 4, the lesser of—

''(i) $25,000,000,000; and

''(ii) the aggregate amount, for all insurers, of insured losses during such Program Year;

''(E) for Program Year 5, the lesser of—

''(i) $27,500,000,000; and

''(ii) the aggregate amount, for all insurers, of insured losses during such Program Year; and

''(F) for each additional Program Year—

''(i) for property and casualty insurance, the lesser of—

''(I) $27,500,000,000; and

''(II) the aggregate amount, for all such insurance, of insured losses during such Program Year; and

''(ii) for group life insurance, the lesser of—

''(I) $5,000,000,000; and

''(II) the aggregate amount, for all such insurance, of insured losses during such Program Year.

''(8) RECOUPMENT OF FEDERAL SHARE.—

''(A) MANDATORY RECOUPMENT AMOUNT.—For purposes of this paragraph, the mandatory recoupment amount for each of the Program Years referred to in subparagraphs (A) through (F) of paragraph (7) shall be the difference between—

''(i) the applicable insurance marketplace aggregate retention amount under paragraph (7) for such Program Year; and

''(ii) the aggregate amount, for all applicable insurers (pursuant to subparagraph (E)), of insured losses during such Program Year that are not compensated by the Federal Government because such losses—

''(I) are within the insurer deductible for the insurer subject to the losses; or

''(II) are within the portion of losses of the insurer that exceed the insurer deductible, but are not compensated pursuant to paragraph (1).

''(B) NO MANDATORY RECOUPMENT IF UNCOMPENSATED LOSSES EXCEED APPLICABLE INSURANCE MARKETPLACE RETENTION.—Notwithstanding subparagraph (A), if the aggregate amount of uncompensated insured losses referred to in clause (ii) of such subparagraph for any Program Year referred to in any of subparagraphs (A) through (F) of paragraph (7) is greater than the applicable insurance marketplace aggregate retention amount under paragraph (7) for such Program Year, the mandatory recoupment amount shall be $0.

''(C) MANDATORY ESTABLISHMENT OF SURCHARGES TO RECOUP MANDATORY RECOUPMENT AMOUNT.—The Secretary shall collect, for repayment of the Federal financial assistance provided in connection with all acts of terrorism (or acts of war, in the case of workers' compensation) occurring during any of the Program Years referred to in any of subparagraphs (A) through (F) of paragraph (7), terrorism loss risk-spreading premiums in an amount equal to any mandatory recoupment amount for such Program Year.

''(D) DISCRETIONARY RECOUPMENT OF REMAINDER OF FINANCIAL ASSISTANCE.—To the extent that the amount of Federal financial assistance provided exceeds any mandatory recoupment amount, the Secretary may—

''(i) recoup, through terrorism loss risk-spreading premiums, such additional amounts; or

''(ii) submit a report to the Congress identifying such amounts that the Secretary believes cannot be recouped, based on—

''(I) the ultimate costs to taxpayers of no additional recoupment;

''(II) the economic conditions in the commercial marketplace, including the capitalization, profitability, and investment returns of the insurance industry and the current cycle of the insurance markets;

''(III) the affordability of commercial insurance for small- and medium-sized businesses; and

''(IV) such other factors as the Secretary considers appropriate.

''(E) SEPARATE RECOUPMENT.—''The Secretary shall provide that—

''(i) any recoupment under this paragraph of amounts paid for Federal financial assistance for insured losses for property and casualty insurance shall be applied to property and casualty insurance policies; and

''(ii) any recoupment under this paragraph of amounts paid for Federal financial assistance for insured losses for group life insurance shall be applied to group life insurance policies.

''(9) POLICY SURCHARGE FOR TERRORISM LOSS RISK-SPREADING PREMIUMS.—

''(A) POLICYHOLDER PREMIUM.—Subject to paragraph (8)(E), any amount established by the Secretary as a terrorism loss risk-spreading premium shall—

''(i) be imposed as a policyholder premium surcharge on property and casualty insurance policies and group life insurance policies in force after the date of such establishment;

''(ii) begin with such period of coverage during the year as the Secretary determines appropriate; and

''(iii) be based on—

''(I) a percentage of the premium amount charged for property and casualty insurance coverage under the policy; and

''(II) a percentage of the amount at risk for group life insurance coverage under the policy.

''(B) COLLECTION.—The Secretary shall provide for insurers to collect terrorism loss risk-spreading premiums and remit such amounts collected to the Secretary.

''(C) PERCENTAGE LIMITATION.—A terrorism loss risk-spreading premium may not exceed, on an annual basis—

''(i) with respect to property and casualty insurance, the amount equal to 3 percent of the premium charged under the policy; and

''(ii) with respect to group life insurance, the amount equal to 0.0053 percent of the amount at risk under the policy.

''(D) ADJUSTMENT FOR URBAN AND SMALLER COMMERCIAL AND RURAL AREAS AND DIFFERENT LINES OF INSURANCE.—

''(i) ADJUSTMENTS.—In determining the method and manner of imposing terrorism loss risk-spreading premiums, including the amount of such premiums, the Secretary shall take into consideration—

''(I) the economic impact on commercial centers of urban areas, including the effect on commercial rents and commercial insurance premiums, particularly rents and premiums charged to small businesses, and the availability of lease space and commercial insurance within urban areas;

''(II) the risk factors related to rural areas and smaller commercial centers, including the potential exposure to loss and the likely magnitude of such loss, as well as any resulting cross-subsidization that might result; and

''(III) the various exposures to terrorism risk for different lines of insurance.

''(ii) RECOUPMENT OF ADJUSTMENTS.—Any mandatory recoupment amounts not collected by the Secretary because of adjustments under this subparagraph shall be recouped through additional terrorism loss risk-spreading premiums.

''(E) TIMING OF PREMIUMS.—The Secretary may adjust the timing of terrorism loss risk-spreading premiums to provide for equivalent application of the provisions of this title to policies that are not based on a calendar year, or to apply such provisions on a daily, monthly, or quarterly basis, as appropriate.

''(f) CAPTIVE INSURERS AND OTHER SELF-INSURANCE ARRANGEMENTS.—The Secretary may, in consultation with the NAIC or the appropriate State regulatory authority, apply the provisions of this title, as appropriate, to other classes or types of captive insurers and other self-insurance arrangements by municipalities and other entities (such as workers' compensation self-insurance programs and State workers' compensation reinsurance pools), but only if such application is determined before the occurrence of an act of terrorism in which such an entity incurs an insured loss and all of the provisions of this title are applied comparably to such entities.

''(g) REINSURANCE TO COVER EXPOSURE.—

''(1) OBTAINING COVERAGE.—This title may not be construed to limit or prevent insurers from obtaining reinsurance coverage for insurer deductibles or insured losses retained by insurers pursuant to this section, nor shall the obtaining of such coverage affect the calculation of such deductibles or retentions.

''(2) LIMITATION ON FINANCIAL ASSISTANCE.—The amount of financial assistance provided pursuant to this section shall not be reduced by reinsurance paid or payable to an insurer from other sources, except that recoveries from such other sources, taken together with financial assistance for the Transition Period or a Program Year provided pursuant to this section, may not exceed the aggregate amount of the insurer's insured losses for such period. If such recoveries and financial assistance for the Transition Period or a Program Year exceed such aggregate amount of insured losses for that period and there is no agreement between the insurer and any reinsurer to the contrary, an amount in excess of such aggregate insured losses shall be returned to the Secretary.

''(h) PRIVILEDGED PROCEDURE FOR JOINT RESOLUTION FOR PAYMENT OF FEDERAL COMPENSATION.—

''(1) IN GENERAL.—The Secretary shall pay the Federal share of compensation under the Program for insured losses resulting from an act of terrorism only if there is enacted a joint resolution for payment of Federal compensation with respect to such act of terrorism.

''(2) JOINT RESOLUTION.—For purposes of this subsection, the term 'joint resolution for payment of Federal compensation' means a joint resolution that—

''(A) does not have a preamble;

''(B) the matter after the resolving clause of which is as follows: 'That the Congress approves of the certification by the Secretary of the Treasury under section 102(1)(A) of the Terrorism Risk Insurance Act of 2002.'; and

''(C) the title of which is as follows: 'To permit Federal compensation under the Terrorism Risk Insurance Act of 2002'.

''(3) INTRODUCTION AND REFERRAL.—Upon receipt of a submission under section 102(1)(G), the joint resolution described in this subsection shall be introduced by the majority leader of each House or his designee (by request). In the case in which a House is not in session, such joint resolution shall be so introduced upon convening the first day of session after the date of receipt of the certification. Upon introduction, the joint resolution shall be referred to the appropriate calendar in each House.

''(4) CONSIDERATION IN THE HOUSE OF REPRESENTATIVES.—

''(A) PROCEEDING TO CONSIDERATION.—Upon referral to the appropriate calendar, it shall be in order to move to proceed to consider the joint resolution in the House. Such a motion shall be in order only at a time designated by the Speaker in the legislative schedule within two legislative days. The previous question shall be considered as ordered on the motion to its adoption without intervening motion. A motion to reconsider the vote by which the motion is disposed of shall not be in order.

''(B) CONSIDERATION.—The joint resolution shall be considered as read. All points of order against teh joint resolution and against its consideration are waived. The previous question shall be considered as ordered on the joint resolution to its passage without intervening motion except one hour of debate equally divided and controlled by a proponent and an opponent and one motion to limit debate on the joint resolution. A motion to reconsider the vote on passage of the joint resolution shall not be in order.

''(5) CONSIDERATION IN THE SENATE.—

''(A) PROCEEDING.—Upon introduction, the joint resolution shall be placed on the Calendar of Business, General Orders. A motion to proceed to the consideration of the joint resolution shall be in order at any time. The motion is privileged and not debatable. A motion to proceed to consideration of the joint resolution may be made even though a previous motion to the same effect has been disagreed to. An amendment to the motion shall not be in order, nor shall it be in order to move to reconsider the vote by which the motion is agreed to.

''(B) DEBATE.—Debate on the joint resolution, and all debatable motions and appeals in connection therewith, shall be limited to not more than ten hours. The time shall be equally divided between and controlled by, the majority leader and the minority leader or their designees.

''(C) DEBATABLE MOTIONS AND APPEALS.—Debate on any debatable motion or appeal in relation to the joint resolution shall be limited to not more than one hour from the time allotted for debate, equally divided and controlled by the majority leader and the minirity leader or their designees.

''(D) MOTION TO LIMIT DEBATE.—A motion to further limit debate is not debatable.

''(E) MOTION TO RECOMMIT.—Any motion to commit or recommit the joint resolution shall not be in order.

''(F) FINAL PASSAGE.—The Chair shall put the question on final passage of the joint resolution no later than 72 hours from the time the measure is introduced.

''(6) AMENDMENTS PROHIBITED.—No amendment to, or motion to strike a provision from, a joint resolution considered under this subsection shall be in order in either the Senate or the House of Representatives.

''(7) CONSIDERATION BY THE OTHER HOUSE.—In the case of a joint resolution described in this subsection, if before passage by one House of a joint resolution of that House, that House receives such joint resolution from the other House, then—

''(A) the procedure in that House shall be the same as if no joint resolution had been received from the other House; but

''(B) the vote on final passage shall be on the joint resolution of the other House.

''(8) HOUSE AND SENATE RULEMAKING.—This subsection is enacted by the Congress as an exercise of the rulemaking power of the house of Representatives and Senate, respectively, and as such is deemed a part of the rules of each House, respectively, and such procedures supersede other rules only to the extent that they are inconsistent with such rules; and with full recognition of the consitutional right of either House to change the rules (so far as relating to the procedures of that House) at any time, in the same manner, and to the same extent as any other rule of that House.'';

(2) in section 104(a)—

(A) in paragraph (1), by striking ''and'' at the end;

(B) in paragraph (2), by striking the period and inserting ''; and''; and

(C) by adding at the end the following new paragraph:

''(3) during the 90-day period beginning upon the certification of any act of terrorism, to issue such regulations as the Secretary considers necessary to carry out this Act without regard to the notice and comment provisions of section 553 of title 5, United States Code.'';

(3) in section 104, by adding at the end the following new subsection:

''(h) ANNUAL ADJUSTMENT.—

''(1) IN GENERAL.—Notwithstanding any other provision of this title, the Secretary shall adjust, for the second additional Program Year and for each additional Program Year thereafter, based upon the percentage change in an appropriate index during the 12-month period preceding such Program Year, each of the following amounts (as such amount may have been previously adjusted):

''(A) The dollar amount in section 102(1)(B)(ii) (relating to act of terrorism).

''(B) The dollar amount in section 102(11)(J) (relating to aggregate industry insured losses in a previously impacted area).

''(C) The dollar amounts in subparagraphs (A) and (B) of section 103(e)(1) (relating to limitation on Federal share).

''(D) The dollar amounts in section 103(e)(1)(C) (relating to Program trigger).

''(E) The dollar amount in section 103(e)(1)(D) (relating to limitation on group life insurance compensation).

''(F) The dollar amounts in section 103(e)(2) (relating to cap on annual liability).

''(G) The dollar amounts in section 103(e)(3)(C) (relating to limitation on insurer financial liability).

''(H) The dollar amounts in section 103(e)(4) (relating to notices regarding losses and annual liability cap).

''(I) The dollar amounts in section 103(e)(7) (relating to insurance marketplace aggregate retention amount).

''(J) The dollar amounts in section 109(b)(1)(C) (relating to membership of Commission on Terrorism Insurance Risk).

''(2) PUBLICATION.—The Secretary shall make the dollar amounts for each additional Program Year, as adjusted pursuant to this subsection, publicly available in a timely manner.'';

(4) in section 106(a)(2)—

(A) in subparagraph (B), by striking ''and'' at the end;

(B) by redesignating subparagraph (C) as subparagraph (F); and

(C) by inserting after subparagraph (B) the following new subparagraphs:

''(C) during the period beginning on the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007 and ending on December 31, 2008, rates and forms for property and casualty insurance, and group life insurance, required by this title and providing coverage except for NBCR terrorism that are filed with any State shall not be subject to prior approval or a waiting period under any law of a State that would otherwise be applicable, except that nothing in this title affects the ability of any State to invalidate a rate as excessive, inadequate, or unfairly discriminatory, and, with respect to forms, where a State has prior approval authority, it shall apply to allow subsequent review of such forms;

''(D) during the period beginning on the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007, and ending on December 31, 2009, forms for property and casualty insurance, and group life insurance, covered by this title and providing coverage for NBCR terrorism that are filed with any State, to the extent of the addition of such coverage for NBCR terrorism and where such coverage was not previously required, shall not be subject to prior approval or waiting period under any law of a State that would otherwise be applicable;

''(E) during the period beginning on the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007, and ending on December 31, 2010, rates for property and casualty insurance, and group life insurance, covered by this title and providing coverage for NBCR terrorism that are filed with any State, to the extent of the addition of such coverage for NBCR terrorism and where such coverage was not previously required, shall not be subject to prior approval or waiting period under any law of a State that would otherwise be applicable, except that nothing in this title affects the ability of any State to invalidate a rate as inadequate or unfairly discriminatory; and'';

(5) in section 106, by adding at the end the following new subsection:

''(c) RULE OF CONSTRUCTION REGARDING INSURER COORDINATION.—Nothing in this Act shall be construed to prohibit, restrict, or otherwise limit an insurer from entering into an arrangement with another insurer to make available coverage for any portion of insured losses to fulfill the requirements of section 103(c). The Secretary shall develop, in consultation with the NAIC, minimum financial solvency standards and other standards the Secretary determines appropriate with respect to such arrangements. Nothing in this subsection shall be construed to establish any legal partnership.''; and

(6) in section 108(c)(1), by striking ''paragraph (4), (5), (6), (7), or (8)'' and inserting ''paragraph (5), (6), (7), (8), or (9)''.

(b) REGULATIONS ON CLAIMS ALLOCATIONS.—The Secretary of the Treasury shall issue the regulations referred to in subparagraph (C) of section 103(e)(2) of the Terrorism Risk Insurance Act of 2002, as amended by subsection (a)(1) of this section, and to carry out subparagraph (B) of such section 103(e)(2), not later than the expiration of the 120-day period beginning upon the date of the enactment of this Act.

(c) REGULATIONS ON NBCR EXEMPTIONS.—The Secretary of the Treasury shall issue the regulations to carry out paragraph (4) of section 103(a) of the Terrorism Risk Insurance Act of 2002, as amended by subsection (a)(1) of this section, not later than the expiration of the 180-day period beginning upon the date of the enactment of this Act.

SEC. 4. TERRORISM BUY-DOWN FUND.

The Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) is amended—

(1) by inserting after section 106 the following new section:

''SEC. 106A. TERRORISM BUY-DOWN FUND.

''(a) ESTABLISHMENT.—The Secretary shall establish a Terrorism Buy-Down Fund (in this section referred to as the 'Fund') that shall make available additional terrorism coverage for the insured losses of insurers, which shall be available for purchase by insurers on a voluntary basis.

''(b) PURCHASE OF DEDUCTIBLE, CO-SHARE, AND TRIGGER BUY-DOWN COVERAGE.—

''(1) IN GENERAL.—An insurer may purchase deductible, co-share, and pre-trigger buy-down coverage (in this section referred to as 'buy-down coverage') through the Fund by making an election, in advance, to treat some or all of

the premiums it has disclosed pursuant to section 106(b)(3) as fee charges for the Program imposed by the Secretary and remitting such amounts to the Fund.

''(2) LIMITS.—An insurer may not purchase buy-down coverage in an amount greater than the lesser of—

''(A) the highest amount specified in section 103(e)(1)(C); and

''(B) the insurer's one-in-one-hundred-year risk exposure to acts of terrorism.

''(c) BUY-DOWN COVERAGE.—The Fund shall provide the buy-down coverage to an insurer for losses for acts of terrorism, without application of the insurer deductible and in addition to any otherwise payable Federal share of compensation pursuant to section 103(e).

''(d) BUILD-UP.—The buy-down coverage that shall be payable to an insurer for qualifying losses shall be the aggregate of the insurer's buy-down coverage premiums plus interest accrued on such amounts.

''(e) USE BY INSURERS.—

''(1) QUALIFYING LOSSES.—For the purpose of this section, qualifying losses are insured losses by an insurer that are not excess losses and that do not include amounts for which Federal financial assistance pursuant to section 103(e) is received, notwithstanding any limits otherwise applicable regarding section 103(e)(1)(C) (regarding program triggers) or section 102(11) (regarding insurer deductibles).

''(2) USE OF BUY-DOWN COVERAGE.—An insurer may use any buy-down coverage payments received under subsection (f) to satisfy—

''(A) the applicable insurer deductibles for the insurer;

''(B) the portion of the insurer's losses that exceed the insurer deductible but are not compensated by the Federal share; and

''(C) the insurer's obligations to pay for insured losses if the Program trigger under section 103(e)(1)(C) is not satisfied.

''(3) BUY-DOWN COVERAGE DOES NOT REDUCE FEDERAL CO-SHARE.—The receipt by an insurer of buy-down coverage under this section for insured losses shall not be considered with respect to calculating the insurer's insured losses with respect to the insurer's deductible and eligibility for Federal financial assistance pursuant to section 103(e).

''(4) INSOLVENCY.—An insurer may sell its rights to buy-down coverage from the Fund to another insurer as part of or to avoid an insolvency or as part of a merger, sale, or major reorganization.

''(f) PAYMENT OF BUY-DOWN COVERAGE.—The Fund shall pay the qualifying losses of an insurer purchasing buy-down coverage up to the amount described in subsection (d).

''(g) GOVERNMENT BORROWING.—The Secretary may borrow the funds from the Fund to offset, in whole or in part, the Federal share of compensation provided to all insurers under the Program, except that—

''(1) the Fund shall always immediately provide any buy-down coverage payments required under subsection (f); and

''(2) any such amounts borrowed must be replenished with appropriate interest.

''(h) RISK-SHARING MECHANISMS.—The Secretary shall establish voluntary risk-sharing mechanisms for insurers purchasing buy-down coverage from the Fund to pool their reinsurance purchases and otherwise share terrorism risk.

''(i) TERMINATION.—Upon termination of the Program under section 108, and subject to the Secretary's continuing authority under section 108(b) to adjust claims in satisfaction under the Program, the Secretary shall provide that the Fund shall become a privately-operated mutual terrorism reinsurance company owned by the insurers that have submitted buy-down coverage premiums in proportion to such premiums minus any buy-down coverage payments received.''; and

(2) in the table of contents in section 1(b), by inserting after the item relating to section 106 the following new item:

''Sec. 106A. Terrorism Buy-Down Fund.''.

SEC. 5. ANALYSIS AND STUDY.

(a) ANALYSIS OF MARKET CONDITIONS.—Section 108 of the Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) is amended by striking subsection (e) and inserting the following:

''(e) ANALYSIS OF MARKET CONDITIONS FOR TERRORISM RISK INSURANCE.—

''(1) IN GENERAL.—The Secretary, in consultation with the NAIC, representatives of the insurance industry, representatives of the securities industry, and representatives of policyholders, shall perform an analysis regarding the long-term availability and affordability of insurance for terrorism risk in the private marketplace, including coverage for—

''(A) property and casualty insurance;

''(B) group life insurance;

''(C) workers' compensation;

''(D) nuclear, biological, chemical, and radiological events; and

''(E) commercial real estate.

''(2) BIENNIAL REPORTS.—The Secretary shall submit biennial reports to the Committee on Financial Services of the House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the Senate, on its findings pursuant to the analysis conducted under paragraph (1). The first such report shall be submitted not later than the expiration of the 24-month period beginning on the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007.

''(3) TESTIMONY.—Upon submission of each biennial report under paragraph (2), the Secretary shall provide oral testimony to the Committee on Financial Services of the House of Representatives and Committee on Banking, Housing, and Urban Affairs of the United States Senate regarding the report and the analysis under this subsection for which the report is submitted.''.

(b) COMMISSION ON TERRORISM RISK INSURANCE.—Title I of the Terrorism Risk Insurance Act of 2002 (15 U.S.C. 6701 note) is amended—

(1) by adding at the end the following new section:

''SEC. 109. COMMISSION ON TERRORISM RISK INSURANCE.

''(a) ESTABLISHMENT.—There is hereby established the Commission on Terrorism Risk Insurance (in this section referred to as the 'Commission').

''(b) MEMBERSHIP.—

''(1) The Commission shall consist of 21 members, as follows:

''(A) The Secretary of the Treasury or the designee of the Secretary.

''(B) One member who is a State insurance commissioner, designated by the NAIC.

''(C) 15 members, who shall be appointed by the President, who shall include—

''(i) a representative of group life insurers;

''(ii) a representative of property and casualty insurers with direct earned premium of $1,000,000,000 or less;

''(iii) a representative of property and casualty insurers with direct earned premium of more than $1,000,000,000;

''(iv) a representative of multiline insurers;

''(v) a representative of independent insurance agents;

''(vi) a representative of insurance brokers;

''(vii) a policyholder representative;

''(viii) a representative of the survivors of the victims of the attacks of September 11, 2001;

''(ix) a representative of the reinsurance industry;

''(x) a representative of workers' compensation insurers;

''(xi) a representative from the commercial mortgage-backed securities industry;

''(xii) a representative from a nationally recognized statistical rating organization;

''(xiii) a real estate developer;

''(xiv) a representative of workers' compensation insurers created by State legislatures, selected in consultation with the American Association of State Compensation Insurance Funds from among its members; and

''(xv) a representative from the commercial real estate brokerage industry or the commercial property management industry.

''(D) Four members, who shall serve as liaisons to the Congress, who shall include two members jointly selected by the Chairman and Ranking Member of the Committee on Financial Services of the House of Representatives and two members jointly selected by the Chairman and Ranking Member of the Committee on Banking, Housing, and Urban Affairs of the Senate.

''(2) SECRETARY.—The Program Director of the Terrorism Risk Insurance Act of the Department of the Treasury shall serve as Secretary of the Commission. The Secretary of the Commission shall determine the manner in which the Commission shall operate, including funding and staffing.

''(c) DUTIES.—

''(1) IN GENERAL.—The Commission shall identify and make recommendations regarding—

''(A) possible actions to encourage, facilitate, and sustain provision by the private insurance industry in the United States of affordable coverage for losses due to an act or acts of terrorism;

''(B) possible actions or mechanisms to sustain or supplement the ability of the insurance industry in the United States to cover losses resulting from acts of terrorism in the event that—

''(i) such losses jeopardize the capital and surplus of the insurance industry in the United States as a whole; or

''(ii) other consequences from such acts occur, as determined by the Commission, that may significantly affect the ability of the insurance industry in the United States to cover such losses independently; and

''(C) possible actions to significantly reduce the Federal role in covering losses resulting from acts of terrorism.

''(2) EVALUATIONS.—In identifying and making the recommendations required under paragraph (1), the Commission shall specifically evaluate the utility and viability of proposals aimed at improving the availability of insurance against terrorism risk in the private marketplace.

''(3) INITIAL MEETING.—The Commission shall hold its first meeting during the 3-month period that begins 15 months after the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007.

''(4) REPORTS.—

''(A) CONTENTS.—The Commission shall submit two reports to the Congress that—

''(i) evaluate and make recommendations regarding whether there is a need for a Federal terrorism risk insurance program;

''(ii) if so, include a specific, detailed recommendation for the replacement of the Program under this title; and

''(iii) include the identifications, evaluations, and recommendations required under paragraphs (1) and (2).

''(B) TIMING.—The first report required under subparagraph (A) shall be submitted before the expiration of the 60-month period beginning on the date of the enactment of the Terrorism Risk Insurance Revision and Extension Act of 2007. The second such report shall be submitted before the expiration of the 96-month period beginning upon such date of enactment.''; and

(2) in the table of contents in section 1(b), by inserting after the item relating to section 108 the following new item:

''Sec. 109. Commission on Terrorism Risk Insurance.''.

SEC. 6. APPLICABILITY.

The amendments made by this Act shall apply beginning on January 1, 2008. The provisions of

the Terrorism Risk Insurance Act of 2002, as in effect on the day before the date of the enactment of this Act, shall apply through the end of December 31, 2007.

Mr. HINOJOSA. Mr. Chairman, I rise today in support of H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act, TRIREA, of 2007, which will both extend and improve upon the current Terrorism Risk Insurance Program.

I am very pleased that the legislation will include domestic terrorism as a covered event. I strongly support the inclusion of group life insurance as a covered line under the new TRIA legislation, and I applaud Chairman FRANK for allowing the return of farm owners multiple peril as a TRIA-covered line.

I want to thank Chairman BARNEY FRANK, Chairman PAUL KANJORSKI, Chairwoman CAROLYN MALONEY and Congressman MICHAEL CAPUANO for working so diligently on this bill and bringing it to the floor today.

At this point, I ask unanimous consent to submit for the record the following letters of support of H.R. 2761: (1) a letter from the American Insurance Association; (2) a letter from the Financial Services Roundtable; (3) a letter from the Coalition to Insure Against Terrorism; and, (4) a letter of support from the Mortgage Bankers Association.

I want to stress one important point that seems to have been lost in the discussion of terrorism overall and the debate on the Terrorism Risk Insurance Act and program in particular.

Mr. Chairman, we are all in this together—not just New York City or Washington, DC, or other large cities but cities both large and small. We must protect all our constituents in all our cities in the United States, and this bill, H.R. 2761 goes a long way towards attaining that goal.

As far as I know, there is no definitive methodology that will determine where terrorists might strike next in the United States. So, we all need to remain vigilant, even those of us from small cities and rural areas. We all need to be prepared, and we all need to help prevent terrorist attacks.

This legislation will help us attain our goals.

For these reasons and more, I encourage my colleagues to vote in favor of H.R. 2761.

AMERICAN INSURANCE ASSOCIATION,
Washington, DC, September 18, 2007.

Hon. NANCY PELOSI,
Speaker, House of Representatives, Washington, DC.
Hon. STENY HOYER,
Majority Leader, House of Representatives, Washington, DC.
Hon. JOHN BOEHNER,
Minority Leader, House of Representatives, Washington, DC.
Hon. ROY BLUNT,
Minority Whip, House of Representatives, Washington, DC.

DEAR SPEAKER PELOSI, MINORITY LEADER BOEHNER, MAJORITY LEADER HOYER, AND MINORITY WHIP BLUNT: We understand that H.R. 2761 is scheduled for House floor consideration tomorrow. We commend the House for moving forward on this critical legislation.

Apart from extending the existing program, H.R. 2761 confronts the unique insurance challenges posed by terrorist threats of a nuclear, biological, chemical or radiological nature (NBCR). In the last two years, two separate government studies—one by the President's Working Group on Financial Markets (led by Treasury) and another by the Government Accountability Office—have concluded what insurers already knew: that, outside of state mandates, there is virtually no private insurance market capacity for NBCR terrorism risk and there is little potential for such a market to emerge in the near future. H.R. 2761 fills that void by requiring insurers to make available additional NBCR terrorism insurance as part of the Federal backstop where policyholders accept the terrorism coverage offered under current law, and by providing insurers with more limited and certain financial exposure that reflects the distinctive catastrophic nature of NBCR terrorism. For this and other reasons, the American Insurance Association and its more than 350 property casualty insurance company members strongly endorse H.R. 2761 as it was reported out of the House Financial Services Committee.

We understand that a new provision has been added to address the concerns resulting from the Congressional Budget Office report, which would require additional Congressional action to authorize Federal payment for an act of terrorism. The industry has serious reservations about the commercial workability and certainty of the provision and the potential adverse marketplace impact. As the legislation moves forward in the process, we look forward to working with you and others in Congress to ensure these concerns are resolved in a way that preserves the future viability of the program.

Sincerely,

MARC RACICOT,
President.

THE FINANCIAL SERVICES ROUNDTABLE,
Washington, DC, September 19, 2007.

Hon. BARNEY FRANK,
Chairman, Committee on Financial Services, House of Representatives, Washington, DC.

DEAR CHAIRMAN FRANK: On behalf of the members of the Financial Services Roundtable, I am writing to express my strong support for H.R. 2761, the ''Terrorism Risk Insurance Revision and Extension Act of 2007 (TRIREA)'' which will extend the public/private partnership created in 2002 to enhance our nation's economic security.

The Terrorism Risk Insurance Act (TRIA) has served as a vital economic policy enabling insurers and policy holders to arrive at commercial insurance agreements that provide adequate coverage for the insured while protecting the solvency of the insurer. Without TRIA, the commercial insurance marketplace faces severe disruption.

H.R. 2761 continues this important partnership, and improves upon it. Notably, the bill extends the program for 15 years, enables coverage for megacatastrophes involving nuclear, biological, chemical and radiological events and covers group life—the only type of life insurance held by most Americans.

I understand that the manager's amendment to the bill makes an essential change to the program making government funds available only after a future congressional action. While generally, we could not support adding contingencies into a bill that is designed to create certainty, I understand the change is necessary to move the bill forward in a timely manner.

As such, I encourage your support for the rule and H.R. 2761 and ask you to oppose any motion to recommit.

Thank you for your consideration of this important matter. Should you have any questions, please do not hesitate to call me, or Andy Barbour of my staff.

Best Regards,

STEVE BARTLETT,
President and CEO.

VOTE ''YES'' ON H.R. 2761

The undersigned members of the Coalition to Insure Against Terrorism (CIAT), a broad based coalition of business insurance policyholders representing a significant segment of the nation's GDP, strongly urge you to vote ''yes'' on H.R. 2761 Terrorism Risk Insurance Revision and Extension Act of 2007 (TRIREA).

American Bankers Association; American Bankers Insurance Association; American Council of Engineering Companies; American Gas Association; American Hotel and Lodging Association; American Land Title Association; American Public Gas Association; American Public Power Association; American Resort Development Association; American Society of Association Executives; Associated Builders and Contractors; Associated General Contractors of America; Association of American Railroads; Association of Art Museum Directors; Babson Capital Management LLC; The Bond Market Association; Building Owners and Managers Association International; Boston Properties; and CCIM Institute.

Campbell Soup Company; Century 21 Department Stores; Chemical Producers and Distributors Association; Citigroup Inc.; Commercial Mortgage Securities Association; Cornerstone Real Estate Advisers, Inc.; CSX Corporation; Edison Electric Institute; Electric Power Supply Association; The Financial Services Roundtable; The Food Marketing Institute; General Aviation Manufacturers Association; Helicopter Association International; Hilton Hotels Corporation; Host Hotels and Resorts; Independent Electrical Contractors; Institute of Real Estate Management; Intercontinental Hotels; and International Council of Shopping Centers.

International Franchise Association; International Safety Equipment Association; The Long Island Import Export Association; Marriott International; Mortgage Bankers Association; National Apartment Association; National Association of Home Builders; National Association of Industrial and Office Properties; National Association of Manufacturers; National Association of REALTORS®; National Association of Real Estate Investment Trusts; National Association of Waterfront Employers; National Association of Wholesaler-Distributors; National Basketball Association; National Collegiate Athletic Association; National Council of Chain Restaurants; National Football League; National Hockey League; and National Multi Housing Council.

National Petrochemical & Refiners Association; National Restaurant Association; National Retail Federation; National Roofing Contractors Association; National Rural Electric Cooperative Association; The New England Council; Partnership for New York City; Office of the Commissioner of Baseball; Public Utilities Risk Management Association; The Real Estate Board of New York; The Real Estate Roundtable; Society of American Florists; Starwood Hotels and Resorts; Taxicab, Limousine & Paratransit Association; Travel Business Roundtable; Trizec Properties, Inc.; UJA-Federation of New York; Union Pacific Corporation; and U.S. Chamber of Commerce.

MORTGAGE BANKERS ASSOCIATION,
Washington, DC, September 17, 2007.

Hon. STENY H. HOYER,
Majority Leader, House of Representatives, Washington, DC.
Hon. JOHN A. BOEHNER,
Republican Leader, House of Representatives, Washington, DC.

DEAR LEADER HOYER AND LEADER BOEHNER: On behalf of the Mortgage Bankers Association (MBA), I am writing to express my strong support for H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act of 2007 and strongly urge Members of the House of Representatives to support the legislation when it comes to the House floor.

H.R. 2761, introduced by Representative Michael Capuano, passed the Committee on Financial Services by a bipartisan vote of 49–20 on August 1, 2007. Significant additions to the prior legislation, the Terrorism Risk Insurance Extension Act of 2005 (TRIEA), include:

Extension of the Terrorism Risk Insurance Act for 15 years;

Coverage of nuclear, biological, chemical or radiological (NBCR) attacks;

Coverage of domestic source terrorism; and

Provision for group life insurance.

The 15-year extension will allow for greater stability in the commercial real estate lending industry where the average loan duration is 10 years. The addition of NBCR coverage will be welcome news to owners and investors in a market where the very limited availability of NBCR terrorism coverage, at any price, has left virtually all properties uninsured against an NBCR event. Given the current concerns about homegrown terrorist acts, particularly since recent events in Europe, the bill extends the program to include acts of domestic terrorism. Finally, the bill includes, for the first time, group life insurance in the program. As a whole, the inclusion of these items in H.R. 2761 eliminates significant terrorism insurance coverage gaps that could inflict great financial damage to American businesses.

Extending TRIEA is essential to continued American economic growth. An inadequate supply of terrorism insurance would potentially trigger bond downgrades, sharply reducing the availability of loan capital for commercial real estate, increasing borrowing costs and undermine economic growth, including employment in the construction and real estate sectors. In fact, conversations with rating agencies indicate that without such a federal backstop, bond downgrades will likely occur, as was the case in the time period between the September 11, 2001 terrorist attacks and the enactment of Terrorism Risk Insurance Act of 2002.

The Terrorism Risk Insurance Revision and Extension Act is strong legislation that will greatly benefit the American economy, giving developers and their investors the constancy they need to work on large-scale real estate projects.

Thank you for the opportunity to share our views on this critical issue. We urge Members of the House of Representatives to support this important legislation.

Sincerely,

JOHN M. ROBBINS,
Chairman.

Mrs. MCCARTHY of New York. Mr. Chairman, I rise in support of H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act of 2007. This legislation extends the TRIA program for 15 years, and it is vital to our Nation.

A longer TRIA means economic certainty and stability in commercial real estate. A longer TRIA means better planning, better rates, and better returns for investors. A longer TRIA is good for the economy.

Financing for major construction often takes more than 10 years. If a project seeks finance for a project in year one of the new TRIA, investors might have the confidence to advance these funds. However, if a project is conceived in year two or year three, and if TRIA is extended for only 10 years, then investors will know that TRIA will be around for only 7 years. The investors may not provide the necessary capital, or those investors may change far more interest than they would under TRIA.

What happens if a community cannot rebuild after an act of terror? Jobs are lost and with them tax revenue from the local to the state and to the federal level. It simply is not rational to believe that somehow a limited TRIA will save money in the long run.

I simply do not believe that the reinsurance industry has the ability or the interest in providing terrorism risk insurance. A federal backup like TRIA is essential.

My colleagues need to remember that TRIA is not a handout and it is not a benefit. The program pays out only in the event of an act of terrorism against the United States; and terrorism is neither a benefit nor a handout.

When one part of America is attacked, the entire country is attacked. When one city or region suffers, then the rest of the country pitches in to help. We have done that in the past after earthquakes, floods, droughts, hurricanes, and acts of terror.

I hope that none of you have to experience what the people of New York, New Jersey, and Connecticut experienced 6 years ago. The next attack may occur in Orlando, Chicago, Los Angeles, or even small cities across this Nation. The people and the government will respond, as we have in the past.

But, TRIA ensures that taxpayers will not have to bear the entire burden of the response. The bill requires insurance companies to do what they do best: provide insurance. Without TRIA, the American taxpayers will have to bear the entire cost of responding to another act of terrorism.

I fully support the TRIA legislation brought before the House today and urge my colleagues to pass the legislation and allow for Senate Action.

Mr. GARRETT of New Jersey. Mr. Chairman, I rise today to voice my very reluctant opposition to the underlying bill.

Over the last 8 months, the Financial Services Committee has had several hearings on this important topic, including one that I attended in New York City. I thought these hearings were very productive and I am pleased that the Committee and this House are focused on an issue that is not only very important to the 5th district of New Jersey, but to our national economic well-being.

After the terrorist attacks of 9/11, terrorism risk insurance either became unavailable or extremely expensive and many businesses were no longer able to purchase insurance that would protect them in any future terrorist attack. Financially, terrorist threats pose a risk of serious harm not only to the insurance industry, but also to the real estate, transportation, construction, energy, and utility sectors. Even beyond the horrific human toll, terrorists could inflict real pain by melting our infrastructure and economy down.

Recognizing the detrimental effects an attack could have upon our economy, Congress acted quickly and responsibly to debate and pass the Terrorism Risk Insurance Act of 2002, better known as TRIA. This temporary Act helped stabilize the terrorism insurance marketplace and restore capacity to that large part of the U.S. economy.

In 2005, Congress extended the TRIA program with some additional reforms and changes for 2 more years. I supported this extension because I felt that more time was needed to allow the private markets increase their capacity and develop new and creative ways to work out the problems that existed.

Since September 11, insurers and reinsurers have cautiously reentered the terrorism insurance market, allocating more capacity year-to-year. More commercial policyholders are becoming insured, year-to-year. At the same time, the federal role has scaled back correspondingly, with higher deductibles, higher co-pays, higher triggers, and fewer lines of insurance covered. I view this increased private-sector involvement and decreased government involvement, to be a positive development.

Unfortunately, the bill before us today sets these positive and natural developments back. Still more unfortunate is that though this is an issue that the Financial Services Committee has historically acted on in a bipartisan manner, the Chairman rebuffed in full and without, what I believe, proper consideration a number of very reasonable proposals that my colleagues on this side of the aisle offered—amendments that might have made this bill more palatable and perhaps staved off the Presidential veto threat now on the table.

My primary concern is the proposed length of duration of the government program. This bill would extend the life of this program by 15 years. A short-term, temporary extension allows for periodic reassessment of market conditions to see if there is more room for private sector participation. It allows for a gradual scaling-back of the government program going-forward as we observe how private insurers and reinsurers continue to expand the market. A short-term extension permits the natural evolution of the market to occur.

Given that the private sector continues to increase its capacity to cover terrorism risk insurance, I believe a short-term extension is more appropriate than creating a permanent government program. If we establish an essentially permanent program, the private sector will lose its incentive to look for innovative and newer solutions.

And realistically passing a 15-year extension is equivalent to passing an essentially permanent program. If we extend the program for too long of a time period, I fear we will not revisit this important topic and continue to try and make improvements like we did after the last time the program expired. As we all know, Congress rarely opens already passed legislation to make changes and improvements. We did not reopen the Transportation Bill, the Farm Bill and other long-term reauthorizations regardless of the problems that arose. And, we will not reopen this bill either.

So, Mr. Chairman, while I would support a temporary extension of this important program, I cannot support extending the program by 15 years, decreasing the amount of private sector participation, and loading an extra burden on the U.S. taxpayer. I ask my colleagues to vote against this legislation.

Mr. PAUL. Mr. Chairman, six years ago, when the Congress considered the bill creating the terrorism insurance program, I urged my colleagues to reject it. One of the reasons I opposed the bill was my concern that, contrary to the claims of the bill's supporters, terrorism insurance would not be allowed to sunset. As I said then:

''The drafters of H.R. 3210 claim that this creates a 'temporary' government program. However, Mr. Speaker, what happens in three years if industry lobbyists come to Capitol Hill to explain that there is still a need for this program because of the continuing threat of terrorist attacks. Does anyone seriously believe that Congress will refuse to reauthorize this

'temporary' insurance program or provide some other form of taxpayer help to the insurance industry? I would like to remind my colleagues that the federal budget is full of expenditures for long-lasting programs that were originally intended to be 'temporary.'"

I am disappointed to be proven correct. I am also skeptical that, having renewed the program twice, this time for fifteen years, Congress will ever allow it to expire.

As Congress considers extending this program, I renew my opposition to it for substantially the same reasons I stated six years ago. However, I do have a suggestion on how to improve the program. Since one claimed problem with allowing the private market to provide terrorism insurance is the difficulty of quantifying the risk of an attack, the taxpayers' liability under the terrorism reinsurance program should be reduced for an attack occurring when the country is under orange or red alert. After all, because the point of the alert system is to let Americans know when there is an increased likelihood of an attack it is reasonable to expect insurance companies to demand that their clients take extra precautionary measures during periods of high alert. Reducing taxpayer subsidies will provide an incentive to ensure private parties take every possible precaution to minimize the potential damage from possible terrorists attack.

Since my fundamental objections to the program remain the same as six years ago, I am attaching my statement regarding H.R. 3210, which created the terrorist insurance program in the 107th Congress:

Mr. Chairman, no one doubts that the government has a role to play in compensating American citizens who are victimized by terrorist attacks. However, Congress should not lose sight of fundamental economic and constitutional principles when considering how best to provide the victims of terrorist attacks just compensation. I am afraid that H.R. 3210, the Terrorism Risk Protection Act, violates several of those principles and therefore passage of this bill is not in the best interests of the American people.

Under H.R. 3210, taxpayers are responsible for paying 90 percent of the costs of a terrorist incident when the total cost of that incident exceeds a certain threshold. While insurance companies technically are responsible under the bill for paying back monies received from the Treasury, the administrator of this program may defer repayment of the majority of the subsidy in order to ''avoid the likely insolvency of the commercial insurer,'' or avoid ''unreasonable economic disruption and market instability.'' This language may cause administrators to defer indefinitely the repayment of the loans, thus causing taxpayers to permanently bear the loss. This scenario is especially likely when one considers that ''avoid . . . likely insolvency, unreasonable economic disruption, and market instability'' are highly subjective standards, and that any administrator who attempts to enforce a strict repayment schedule likely will come under heavy political pressure to be more ''flexible'' in collecting debts owed to the taxpayers.

The drafters of H.R. 3210 claim that this creates a ''temporary'' government program. However, Mr. Speaker, what happens in three years if industry lobbyists come to Capitol Hill to explain that there is still a need for this program because of the continuing threat of terrorist attacks. Does anyone seriously believe that Congress will refuse to reauthorize this ''temporary'' insurance program or provide some other form of taxpayer help to the insurance industry? I would like to remind my colleagues that the federal budget is full of expenditures for long-lasting programs that were originally intended to be ''temporary.''

H.R. 3210 compounds the danger to taxpayers because of what economists call the ''moral hazard'' problem. A moral hazard is created when individuals have the costs incurred from a risky action subsidized by a third party. In such a case individuals may engage in unnecessary risks or fail to take steps to minimize their risks. After all, if a third party will bear the costs of negative consequences of risky behavior, why should individuals invest their resources in avoiding or minimizing risk?

While no one can plan for terrorist attacks, individuals and businesses can take steps to enhance security. For example, I think we would all agree that industrial plants in the United States enjoy reasonably good security. They are protected not by the local police, but by owners putting up barbed wire fences, hiring guards with guns, and requiring identification cards to enter. One reason private firms put these security measures in place is because insurance companies provide them with incentives, in the form of lower premiums, to adopt security measures. H.R. 3210 contains no incentives for this private activity. The bill does not even recognize the important role insurance plays in providing incentives to minimize risks. By removing an incentive for private parties to avoid or at least mitigate the damage from a future terrorist attack, the government inadvertently increases the damage that will be inflicted by future attacks!

Instead of forcing taxpayers to subsidize the costs of terrorism insurance, Congress should consider creating a tax credit or deduction for premiums paid for terrorism insurance, as well as a deduction for claims and other costs borne by the insurance industry connected with offering terrorism insurance. A tax credit approach reduces government's control over the insurance market. Furthermore, since a tax credit approach encourages people to devote more of their own resources to terrorism insurance, the moral hazard problems associated with federally funded insurance is avoided.

The version of H.R. 3210 passed by the Financial Services committee took a good first step in this direction by repealing the tax penalty which prevents insurance companies from properly reserving funds for human-created catastrophes. I am disappointed that this sensible provision was removed from the final bill. Instead, H.R. 3210 instructs the Treasury Department to study the benefits of allowing insurers to establish tax-free reserves to cover losses from terrorist events. The perceived need to study the wisdom of cutting taxes while expanding the federal government without hesitation demonstrates much that is wrong with Washington.

In conclusion, Mr. Chairman, H.R. 3210 may reduce the risk to insurance companies from future losses, but it increases the costs incurred by the American taxpayer. More significantly, by ignoring the moral hazard problem this bill may have the unintended consequence of increasing the losses suffered in any future terrorist attacks. Therefore, passage of this bill is not in the long-term interests of the American people.

Mr. LARSON of Connecticut. Mr. Chairman, today I rise in strong support of H.R. 2761, the Terrorism Risk Insurance Revision and Extension Act of 2007, which would reauthorize the Federal terrorism insurance program (TRIA) for 15 years.

I am pleased that the years spent working on this issue with constituents, the insurance industry, and the financial services industries to build a consensus has produced a bill so widely supported by Members in the House on both sides of the aisle that has the strong support of the business community. I applaud Chairman FRANK, the members of the House Financial Services Committee, and Representative CAPUANO, the chief sponsor of the bill, for their leadership in crafting this critical legislation protecting the safety and security of America.

It is estimated that the September 11th terrorist attacks resulted in $40 billion in insured claims, the largest man-made insurance disaster on record. After the 9/11 attacks, given the size of potential liabilities, there was growing concern that insurance companies and reinsurers might not be able to write policies to insure losses due to future acts of terrorism. As a result, the TRIA program was enacted in 2002 in an attempt to prevent an industry-wide catastrophe in the event of another domestic terrorist attack. The TRIA program provides a federal backstop to the insurance industry by providing compensation for a portion of insured losses resulting from acts certified by the Government as acts of terrorism. The law was reauthorized with some changes in 2005 (P.L. 109–44) and will expire on December 31, 2007.

Currently, TRIA only covers foreign terrorism; however, this bill would extend TRIA coverage to both foreign and domestic terrorism. The bill would set the ''trigger'' level—the size of an attack at which the Federal Government would provide aid to insurers—at $50 million. According to studies from the Government Accountability Office (GAO), the risk of nuclear, biological, chemical and radiological terrorism is uninsurable absent a Federal Government backstop. In response, this legislation would include acts of nuclear, biological, chemical, and radiological terrorism in TRIA. The bill would also add group life insurance to the types of insurance for which terrorism insurance coverage must be made available by insurers. Finally, H.R. 2761 would create a 21-member ''blue ribbon'' commission to propose long-term solutions to covering terrorism risk. The goal of this legislation is to protect America's economy during a time of national crisis and is important to the economic security of the business community in Hartford and the Capital Region.

I urge my colleagues to vote in favor of final passage and for the President to sign this bill into law. The continued insurance and safety of our Nation against terrorist attacks is an urgent and bipartisan issue.

The CHAIRMAN. No further amendment to the bill, as amended, is in order except those printed in part B of the report. Each further amendment may be offered only in the order printed in the report, by a Member designated in the report, shall be considered read, shall be debatable for the time specified in the report, equally divided and controlled by the proponent and an opponent, shall not be subject

to amendment, and shall not be subject to a demand for division of the question.

AMENDMENT NO. 1 OFFERED BY MR. FRANK OF MASSACHUSETTS

The CHAIRMAN. It is now in order to consider amendment No. 1 printed in House Report 110–333.

Mr. FRANK of Massachusetts. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 1 offered by Mr. FRANK of Massachusetts:

Strike section 102(1)(C) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, and insert the following:

''(C) CERTIFICATION OF ACT OF NBCR TERRORISM.—Where a certified act of terrorism is carried out by means of a nuclear, biological, chemical, or radiological weapon or similar instrumentality, the Secretary shall further certify such act of terrorism as an act of NBCR terrorism. If a certified act of terrorism involves any other weapon or instrumentality, the Secretary, in concurrence with the Secretary of State, the Secretary of Homeland Security, and the Attorney General of the United States, shall determine whether the act of terrorism meets the definition of NBCR terrorism in this section. If such determination is that the act does meet such definition, the Secretary shall further certify that such act as an act of NBCR terrorism. Nothing in this subparagraph shall prohibit the Secretary from determining that a single act of terrorism resulted in both NBCR and non-NBCR insured losses.''.

In section 102(11)(I)(ii)(II) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, strike ''and'' at the end.

In section 102(11)(J)(i) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, add ''and'' at the end.

In section 102(11)(J) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, strike the period at the end and insert ''; and''.

At the end of section 102(11) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, add the following:

''(K) for the fifth additional Program Year and any Additional Program year thereafter, notwithstanding subparagraph (I)(i), if aggregate industry insured losses resulting from a certified act of NBCR terrorism exceed $1,000,000,000, for any insurer that sustains insured losses resulting from such act of NBCR terrorism, the value of such insurer's direct earned premiums over the calendar year immediately preceding the Program Year, multiplied by a percentage, which—

''(i) for the fifth additional Program Year shall be 5 percent; and

''(ii) for each additional Program Year thereafter, shall be 50 basis points greater than the percentage applicable to the preceding additional Program Year, except that if an act of NBCR terrorism occurs during the fifth additional Program Year or any additional Program Year thereafter that results in aggregate industry insured losses exceeding $1,000,000,000, the percentage for the succeeding additional Program Year shall be 5 percent and the increase under this clause shall apply to additional Program Years thereafter;

except that for purposes of determining under this subparagraph whether aggregate industry insured losses exceed $1,000,000,000, the Secretary may combine insured losses resulting from two or more certified acts of NBCR terrorism occurring during such Program Year in the same geographic area (with such area determined by the Secretary), in which case such insurer shall be permitted to combine insured losses resulting from such acts of NBCR terrorism for purposes of satisfying its insurer deductible under this subparagraph; and except that the insurer deductible under this subparagraph shall apply only with respect to compensation of insured losses resulting from such certified act, or combined certified acts, and that for purposes of compensation of any other insured losses occurring in the same Program Year, the insurer deductible determined under subparagraph (I)(i) shall apply.''.

In section 102(13) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, strike ''involves nuclear, biological'' and all that follows and insert ''involves or triggers nuclear, biological, chemical, or radiological reactions, releases, or contaminations, but only if any aggregate industry insured losses that result from such reactions, releases, or contaminations exceed the amount set forth in paragraph (1)(B)(ii).''.

In section 103(c)(4)(A)(iii)(II)(aa) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, strike ''unlawful'' and insert ''fraudulent''.

In section 103(c)(4)(A)(iii)(II)(bb) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, after ''insured person is'' insert ''substantially''.

In section 103(e)(1)(B)(ii) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, insert ''result from any such reactions, releases, or contaminations and that'' after ''such insured losses that'' .

In section 103(e)(1)(B)(ii)(I) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, strike ''exceeds'' and insert ''exceed''.

In section 103(h)(1) of the Terrorism Risk Insurance Act of 2002, in the matter preceding subparagraph (A), as proposed to be amended by section 3(a)(1) of the bill, strike ''an appropriate index'' and all that follows through the colon and insert ''the Consumer Price Index for All Urban Consumers (CPI–U), as published by the Bureau of Labor Statistics of the Department of Labor, during the 12-month period preceding such program year, each of the dollar amounts set forth in this title (as such amount may have been previously adjusted), including the following amounts:''.

Strike subparagraph (B) of section 103(h)(1) of the Terrorism Risk Insurance Act of 2002, as proposed to be amended by section 3(a)(1) of the bill, and insert the following:

''(B) The dollar amounts in subparagraphs (J) and (K) of section 102(11) (relating to an insurer deductible threshold based on the amount of aggregate industry insured losses).''.

In section 3 of the bill, redesignate subsection (c) as subsection (d).

In section 3 of the bill, after subsection (b) insert the following new subsection:

(c) REGULATIONS ON CERTIFICATION OF AN ACT OF NBCR TERRORISM.—The Secretary of the Treasury shall issue the regulations to carry out subparagraph (C) of section 102(1) of the Terrorism Risk Insurance Act of 2002, as amended by subsection (a)(1) of this section, not later than the expiration of the 180-day period beginning upon the date of the enactment of this Act.

The CHAIRMAN. Pursuant to House Resolution 660, the gentleman from Massachusetts (Mr. FRANK) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from Massachusetts.

Mr. FRANK of Massachusetts. Mr. Chairman, I recognize myself for 1 minute.

Mr. Chairman, this is an agreed-upon set of amendments. As I said, it was a bipartisan process, to some extent, in drafting. This makes technical revisions and requires Treasury to promulgate rules to clarify the nuclear, biological, chemical and radiation certification process. It provides that there be indexing, which is, I think, in accordance, there are some copayments, et cetera, and these will be indexed. It applies the reset mechanism to the deductible for nuclear, biological, chemical and radiological, and it makes technical and conforming changes. I believe, as I said, this represents a consensus.

Mr. Chairman, I reserve the balance of my time.

Mr. BACHUS. Mr. Chairman, I rise to claim time in opposition, although I am not opposed to the manager's amendment.

The CHAIRMAN. Without objection, the gentleman from Alabama is recognized for 5 minutes.

There was no objection.

Mr. BACHUS. Mr. Chairman, this amendment has some improvements to the bill. I would like to express to the chairman that I appreciate his willingness to work to make, I think, some needed and technical changes to the bill. I would encourage my colleagues to vote for the manager's amendment and, again, express, although the chairman and I have some philosophical differences in the overall TRIA legislation and whether how temporary it ought to be or how permanent it ought to be or the extent of where the Federal subsidies, on this amendment we have no disagreement.

We continue to work well in a bipartisan manner despite our philosophical differences.

Mr. Chairman, I urge Members to support the manager's amendment.

Mr. Chairman, I yield back the balance of my time.

Mr. FRANK of Massachusetts. Mr. Chairman, I thank the ranking member. We were able to work out a number of these things. I would just want to return to a couple of broader points. I want to make two points. One, I don't think the market will work and neither does any participant in the market either as an insurer, or any significant number, or as the insured. But even if it could, it does not seem to me that it should. If you did this purely in the private market, you would give to the vicious attackers of America the power to decide that it would be more

expensive to do business in some parts of our country than others. You could have another video from the despicable Osama Bin Laden in which he could threaten that he would take action against this area or that area, these facilities or those facilities, and their insurance premiums would go up.

Yes, the private market should govern all those things which it deals with, with fire and with other forms of casualty and even with natural disasters. But to put in the hands of America's enemies this economic power is a grave error. Should the taxpayers pay for it? Yes, because it is a matter of national defense. It is a matter of homeland security. We are not talking about insuring people against the risk if they built a commercial building of liability to injury, of fire, of theft, of improper or inadequate construction. We are saying that, no, if you are in business in America, you should not have to insure against an attack on this country based on hatred of us.

So that is why I believe that we should do this as a public policy matter.

Mr. Chairman, at this point, I yield 2 minutes to the gentleman from North Carolina, a member of the committee who is one of our most thoughtful Members to discuss the general principle of the bill.

Mr. WATT. I am actually walking into the floor at a good time to pick up on the point that the Chair of the committee is making.

This has kind of turned out to be the kind of debate that you hear in politics: Democrats believe in government and government can do everything; and Republicans believe in the private sector, and the private sector can do everything. The truth of the matter is neither one of those things is correct. There are some things that government can do and there are some things, a lot of things, that the private sector can do. One thing I think the private sector cannot do effectively is to insure against the kind of things that are really governmental responsibilities, protection of ourselves, our national defense. When that fails, it becomes a responsibility of government to accept and provide a safety net for our business community, or for our people.

It is unfortunate that this debate has deteriorated into that kind of dichotomy. You have to either have all of government or all of the private sector.

We think this is an ideal time for the government to be providing this kind of insurance protection so that business and the private sector and real estate development can continue to operate without fear of intervention by foreign powers or terrorists.

And I rise in support of the amendment

□ 1330

Mr. BACHUS. Mr. Chairman, I ask unanimous consent to reclaim 30 seconds of my time.

The CHAIRMAN. Is there objection to the request of the gentleman from Alabama?

There was no objection.

Mr. BACHUS. I thank the Chairman.

Let me say to all Members of this body, we are not saying and neither has it been our position that the government does not have a role to play in offering a backstop to terrorist insurance. We believe that that ought to be a limited goal, and we believe that we ought to continue in the path of the prior TRIA extensions, where we continue to let the private market fill in.

We believe, on the other hand, and we not only believe, but this bill calls for higher deductibles, higher premiums and higher taxpayer participation, and we feel like we are reversing our role

The CHAIRMAN. The question is on the amendment offered by the gentleman from Massachusetts (Mr. FRANK).

The question was taken; and the Chairman announced that the ayes appeared to have it.

Mr. PEARCE. Mr. Chairman, I demand a recorded vote.

The CHAIRMAN. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from Massachusetts will be postponed.

AMENDMENT NO. 2 OFFERED BY MR. PEARCE

The CHAIRMAN. It is now in order to consider amendment No. 2 printed in part B of House Report 110–333.

Mr. PEARCE. Mr. Chairman, I have an amendment at the desk.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 2 offered by Mr. PEARCE:

In the matter proposed to be added by the amendment made by section 3(a)(1) of the bill, in section 102(11)(J)(ii), strike ''50 basis points'' and insert ''100 basis points''.

The CHAIRMAN. Pursuant to House Resolution 660, the gentleman from New Mexico (Mr. PEARCE) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentleman from New Mexico.

Mr. PEARCE. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I rise today to offer an amendment to the Terrorism Risk Insurance Revision and Extension Act of 2007. My amendment takes one critical step forward in writing insurer participation back into TRIA.

Five years ago, the Terrorism Risk Insurance Act, TRIA, was signed into law as a temporary program to facilitate transition to a viable market for private terrorism insurance. Since enacting TRIA in 2002, insurer deductibles have increased incrementally by at least 2.5 percent each year, from 7 percent in the first year to the current 20 percent level.

The bill before us today scales back insurance industry participation in the terrorism risk market and reduces the expectation that a private market will one day take over. H.R. 2761 would lower the 20 percent deductible to 5 percent, increasing by one-half percent each year for events above $1 billion. At that rate, it would take 30 years before the deductibles would reach today's level, where Treasury assures us the market is performing very well.

While I am supportive of TRIA as a concept and understand the market is not yet where it needs to be to take over terrorism insurance, I believe strongly that the responsibility for terrorism insurance needs to be on the insurers, not on the taxpayers.

My amendment will rewrite some of the insurance industry participation back into TRIA. I have proposed a modest increase in deductible each year of 1 percent, an increase of one-half percent from where the bill is today. It will ensure that deductibles are back up to the current 20 percent level at the end of the 15-year extension.

I believe my amendment is a step in the right direction towards encouraging a private terrorism insurance market, while providing the insurance industry with the environment for a stable transition. I hope that you will join me in supporting this important amendment.

Mr. Chairman, I reserve the balance of my time.

Mr. ACKERMAN. Mr. Chairman, I rise to claim the time in opposition.

The CHAIRMAN. The gentleman from New York is recognized for 5 minutes.

Mr. ACKERMAN. Mr. Chairman, our friends on the Republican side pride themselves on being tough on terror, and rightfully so. To be honest, it is evident when you listen to President Bush and he says things like ''You're either with us or against us.''

But also the President said in the wake of 9/11, he said this here in this Chamber to the Congress and to the American people, and I quote our President, ''Terrorist attacks can shake the foundations of our biggest buildings, but they cannot touch the foundations of America. These acts shatter steel, but they cannot dent the steel of American resolve.'' Our President said that to us, Mr. Chairman.

After looking over the amendment, I realize the gentleman from New Mexico was not yet elected to be here and probably didn't get the memo about what the President said, because the effect of his amendment would allow terrorists to tell us where we can and where we cannot build after a catastrophic terrorist attack.

The bill would reset the deductible from 20 percent to 5 percent after a terrorist attack, which is good. The amendment that the gentleman proposes would increase the reset deductible to as high as 19 percent after a terrorist attack, which is almost the same as the original 20 percent. Small comfort.

Undermining the purpose and the intent of the reset mechanism by eliminating the incentives created by the reset would price insurers out of areas affected by terrorist attacks, prohibiting developers from rebuilding.

It would seem to me that to support this amendment is so blatantly to oppose the American resolve that President Bush claimed in the wake of September 11. Should we have left Ground Zero smoldering and not build the Freedom Tower? Should we concede defeat to Osama bin Laden? Should he dictate where we can and cannot build?

I say to the gentleman from New Mexico, if we cannot build and rebuild in the areas where terrorists attack, that is a major defeat for our country and a resounding retreat from the spirit of our Nation.

I yield to the gentleman from Massachusetts, the chairman of the committee.

Mr. FRANK of Massachusetts. I join the gentleman in opposition, and I want to address this charge that we heard from one of the Members that this is a typical liberal Democratic bigspending program.

I will include for the RECORD a strong endorsement of H.R. 2761 from the Coalition to Insure Against Terrorism. It is composed of such traditional liberal groups as the American Bankers Association, the National Apartment Association, the National Association of Manufacturers, the U.S. Chamber of Commerce, the National Retail Federation, the National Restaurant Association and the National Association of Industrial and Office Property. Virtually every business involved in this, the Financial Services Roundtable, led by that radical, our former colleague, Mr. Bartlett of Texas, every business group from the insuring and insured part says this is not for the market.

I would add also a letter from the National League of Cities strongly urging on behalf of the cities of America passage of this bill as it was reported out of committee.

Finally, from the American Insurance Association, a strong argument. In particular, it thanks us for including nuclear, biological, chemical and radiological.

Those who said the market can do it, it says two separate government studies have concluded what insurers already knew, that outside of State mandates, there is virtually no private insurance market capacity for NBCR. ''For this and other reasons,'' they like the whole bill, ''the American Insurance Association and its more than 350 property casualty insurance companies strongly endorse H.R. 2761 as it was reported out of the committee.'' They have got some concern about the reset, and we will talk about that and we agree with them. But here is this strong endorsement.

Yes, it is true that this is something that some liberal Democrats support. And here is the signer on behalf of the American Insurance Association, Governor Marc Racicot, I believe a former chairman of the Republican National Committee. I want to congratulate my Democratic colleagues. To have insinuated a liberal Democrat into the chairmanship of the Republican National Committee is a degree of flexibility I didn't know we have.

So this notion that this is some liberal invention and that the market can do it is repudiated by everyone who knows anything about the market. I hope the amendment is defeated and the bill is passed.

VOTE ''YES'' ON H.R. 2761

The undersigned members of the Coalition to Insure Against Terrorism (CIAT), a broad based coalition of business insurance policyholders representing a significant segment of the nation's GDP, strongly urge you to vote ''yes'' on H.R. 2761 Terrorism Risk Insurance Revision and Extension Act of 2007 (TRIREA).

American Bankers Association; American Bankers Insurance Association; American Council of Engineering Companies; American Gas Association; American Hotel and Lodging Association; American Land Title Association; American Public Gas Association; American Public Power Association; American Resort Development Association; American Society of Association Executives; Associated Builders and Contractors; Associated General Contractors of America; Association of American Railroads; Association of Art Museum Directors; Babson Capital Management LLC; The Bond Market Association; Building Owners and Managers Association International; Boston Properties; and CCIM Institute.

Campbell Soup Company; Century 21 Department Stores; Chemical Producers and Distributors Association; Citigroup Inc.; Commercial Mortgage Securities Association; Cornerstone Real Estate Advisers, Inc.; CSX Corporation; Edison Electric Institute; Electric Power Supply Association; The Financial Services Roundtable; The Food Marketing Institute; General Aviation Manufacturers Association; Helicopter Association International; Hilton Hotels Corporation; Host Hotels and Resorts; Independent Electrical Contractors; Institute of Real Estate Management; Intercontinental Hotels; and International Council of Shopping Centers.

International Franchise Association; International Safety Equipment Association; The Long Island Import Export Association; Marriott International; Mortgage Bankers Association; National Apartment Association; National Association of Home Builders; National Association of Industrial and Office Properties; National Association of Manufacturers; National Association of REALTORS®; National Association of Real Estate Investment Trusts; National Association of Waterfront Employers; National Association of Wholesaler-Distributors; National Basketball Association; National Collegiate Athletic Association; National Council of Chain Restaurants; National Football League; National Hockey League; and National Multi Housing Council.

National Petrochemical & Refiners Association; National Restaurant Association; National Retail Federation; National Roofing Contractors Association; National Rural Electric Cooperative Association; The New England Council; Partnership for New York City; Office of the Commissioner of Baseball; Public Utilities Risk Management Association; The Real Estate Board of New York; The Real Estate Roundtable; Society of American Florists; Starwood Hotels and Resorts; Taxicab, Limousine & Paratransit Association; Travel Business Roundtable; Trizec Properties, Inc.; UJA-Federation of New York; Union Pacific Corporation; and U.S. Chamber of Commerce.

AMERICAN INSURANCE ASSOCIATION,
Washington, DC, September 18, 2007.

Hon. NANCY PELOSI,
Speaker, House of Representatives, Washington, DC.
Hon. STENY HOYER,
Majority Leader, House of Representatives, Washington, DC.
Hon. JOHN BOEHNER,
Minority Leader, House of Representatives, Washington, DC.
Hon. ROY BLUNT,
Minority Whip, House of Representatives, Washington, DC.

DEAR SPEAKER PELOSI, MINORITY LEADER BOEHNER, MAJORITY LEADER HOYER, AND MINORITY WHIP BLUNT: We understand that H.R. 2761 is scheduled for House floor consideration tomorrow. We commend the House for moving forward on this critical legislation.

Apart from extending the existing program, H.R. 2761 confronts the unique insurance challenges posed by terrorist threats of a nuclear, biological, chemical or radiological nature (NBCR). In the last two years, two separate government studies—one by the President's Working Group on Financial Markets (led by Treasury) and another by the Government Accountability Office—have concluded what insurers already knew: that, outside of state mandates, there is virtually no private insurance market capacity for NBCR terrorism risk and there is little potential for such a market to emerge in the near future. H.R.2761 fills that void by requiring insurers to make available additional NBCR terrorism insurance as part of the Federal backstop where policyholders accept the terrorism coverage offered under current law, and by providing insurers with more limited and certain financial exposure that reflects the distinctive catastrophic nature of NBCR terrorism. For this and other reasons, the American Insurance Association and its more than 350 property casualty insurance company members strongly endorse H.R. 2761 as it was reported out of the House Financial Services Committee.

We understand that a new provision has been added to address the concerns resulting from the Congressional Budget Office report, which would require additional Congressional action to authorize Federal payment for an act of terrorism. The industry has serious reservations about the commercial workability and certainty of the provision and the potential adverse marketplace impact. As the legislation moves forward in the process, we look forward to working with you and others in Congress to ensure these concerns are resolved in a way that preserves the future viability of the program.

Sincerely,

GOVERNOR MARC RACICOT,
President, American Insurance Association.

NATIONAL LEAGUE OF CITIES,
Washington, DC, September 19, 2007.

Hon. BARNEY FRANK,
Chairman, House of Representatives, Committee on Financial Services, Rayburn House Office Building, Washington, DC.
Hon. SPENCER BACHUS,
Ranking Member, House of Representatives, Committee on Financial Services, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN FRANK AND RANKING MEMBER BACHUS: I am writing on behalf of the 19,000 cities and towns represented by the National League of Cities to express our support for the Terrorism Risk Insurance Revision and Extension Act of 2007, H.R. 2761.

The Terrorism Risk Insurance Act (TRIA) creates an important mechanism under which the Federal government provides a vital federal backstop to potential catastrophic loss caused by terrorism. In addition to safeguarding America's economy and

stabilizing the terrorism insurance marketplace, TRIA provides the necessary direct federal insurance assistance to state and local governments in the case of terrorist acts.

The Act would extend the Terrorism Insurance Program for a sufficient time period to assure local governments that adequate and affordable insurance against losses caused by terrorism is readily available in the marketplace. The legislation also extends coverage to domestic acts of terrorism, which will add an additional level of protection against losses to America's cities and towns.

For these reasons, NLC supports H.R. 2761. We thank you for your leadership on this important legislation and look forward to working with you to ensure its passage.

Sincerely yours,

DONALD J. BORUT,
Executive Director.

Mr. PEARCE. Mr. Chairman, I yield 30 seconds to the gentleman from Alabama (Mr. BACHUS).

Mr. BACHUS. Mr. Chairman, I want to thank the chairman of the full committee for reading that list of those that endorsed it. You will notice that some of the absences were the Consumer Federation of America, which said that this bill was not good for consumers, i.e. taxpayers. The National Taxpayers Association obviously wasn't on that list, because it is a great deal for the insurance companies, and we all acknowledge that. It merely subsidizes them at the expense of taxpayers. The one name missing is taxpayers. They will pay for this legislation.

Mr. ACKERMAN. Mr. Chairman, I further yield to the gentleman from Massachusetts (Mr. FRANK).

Mr. FRANK of Massachusetts. I would say yes, the taxpayers do pay. It is a matter of national defense. Where people are building and incurring risks, they should pay for it themselves. I accept that point. We are talking about how we respond to Osama bin Laden or other murderers who would attack this country.

I think it is appropriate that the country as a whole respond, and not allow the terrorists to pick and choose which Americans will have to suffer disproportionately.

Mr. PEARCE. Mr. Chairman, I find the comments very strange from the opponents of the amendment. They say that my amendment will stop rebuilding and let Osama bin Laden tell us where to rebuild.

Currently the rate of insurance deductible is at 20 percent. The rebuilding is going on quite well, frankly, and they have sustained 2.5 percent increases through the past 6 years. What we are simply saying is we are going to start at 5 percent and increase 1 percent a year over 15 years back up to the 20 percent level. Yet we are being told that regardless of what is being built now, something is going to change in the equation and the people are going to stop rebuilding if we go up and go to this one-half percent increase.

I find it heartening to know that we are within a half percent of stopping the entire economy of the U.S. on a one-half percent deductible and giving over our independence to the terrorists based on this one-half percent, when the truth is the last 6 years showed us that the industry will sustain 2.5 percent increases and continue to build exactly where they want to build, and in fact the industry will sustain on its own at least up to 20 percent. If we are estimating something above that, that would be unchartered territory. But I do find the arguments somewhat stunning.

I reserve the balance of my time.

Mr. ACKERMAN. Mr. Chairman, we have no further speakers. I would just urge all of our colleagues to join with the former chairman of the Republican National Committee and Mr. FRANK and myself and oppose this amendment before the House.

Mr. Chairman, I yield back the balance of my time.

Mr. PEARCE. Mr. Chairman, I have no other speakers and would just urge Members to support the amendment so that we can convert this public program back into a private program over a long course of time.

Mrs. MALONEY of New York. Mr. Chairman, I rise in strong opposition to this amendment. This amendment effectively guts a provision of this bill which is essential for the recovery of localities that are the subject of terrorist attacks.

As we know in New York, insurance companies are reluctant to write coverage at all for sites of terrorist attacks because they find the risk of another attack too high given the deductible under TRIA. Insurance companies aren't willing to pay the higher deductible more than once, in other words, for any given site. We in New York face this problem today as there is far less coverage available for lower Manhattan than is required, but this problem will confront any locality that is the subject of an attack.

The reset mechanism in the bill solves this problem by lowering the deductible for any locality that has been the subject of a significant attack. It applies nationally and will greatly help with economic recovery by helping to provide adequate terrorism insurance.

We have worked on a bipartisan basis to make sure this reset mechanism works for the whole Nation, for industry, for policy holders and that it is fiscally responsible.

This amendment guts the reset mechanism by mandating large and rapid increases in the deductible once it resets to a lower number after a large terrorist attack.

Under this amendment, the reset deductible could rise in a short time to as high as 19 percent, which is almost the same as the original deductible of 20 percent. This defeats the purpose of the reset mechanism, which we worked so hard to craft as a balanced and effective tool.

A TRIA bill that does not consider the special problems of sites recovering from an attack is not an effective or well designed plan.

I urge my colleagues to reject this misguided amendment.

Mr. PEARCE. Mr. Chairman, I yield back the balance of my time.

The CHAIRMAN. The question is on the amendment offered by the gentleman from New Mexico (Mr. PEARCE).

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. PEARCE. Mr. Chairman, I demand a recorded vote.

The CHAIRMAN. Pursuant to clause 6 of rule XVIII, further proceedings on the amendment offered by the gentleman from New Mexico will be postponed.

ANNOUNCEMENT BY THE CHAIRMAN

The CHAIRMAN. Pursuant to clause 6 of rule XVIII, proceedings will now resume on those amendments on which further proceedings were postponed, in the following order:

Amendment No. 1 printed in part B by Mr. FRANK of Massachusetts;

Amendment No. 2 printed in part B by Mr. PEARCE of New Mexico.

The Chair will reduce to 5 minutes the time for the second electronic vote in this series.

AMENDMENT NO. 1 OFFERED BY MR. FRANK OF MASSACHUSETTS

The CHAIRMAN. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from Massachusetts (Mr. FRANK) on which further proceedings were postponed and on which the ayes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The CHAIRMAN. A recorded vote has been demanded.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 426, noes 1, not voting 10, as follows:

[Roll No. 881]

AYES—426

Abercrombie	Boustany	Conyers
Ackerman	Boyd (FL)	Cooper
Aderholt	Boyda (KS)	Costa
Akin	Brady (PA)	Costello
Alexander	Brady (TX)	Courtney
Altmire	Braley (IA)	Cramer
Andrews	Broun (GA)	Crenshaw
Arcuri	Brown (SC)	Crowley
Baca	Brown, Corrine	Cuellar
Bachmann	Brown-Waite, Ginny	Culberson
Bachus	Buchanan	Cummings
Baird	Burgess	Davis (AL)
Baker	Burton (IN)	Davis (CA)
Baldwin	Butterfield	Davis (IL)
Barrett (SC)	Buyer	Davis (KY)
Barrow	Calvert	Davis, David
Bartlett (MD)	Camp (MI)	Davis, Lincoln
Barton (TX)	Campbell (CA)	Davis, Tom
Bean	Cannon	Deal (GA)
Becerra	Cantor	DeFazio
Berkley	Capito	DeGette
Berman	Capps	Delahunt
Berry	Capuano	DeLauro
Biggert	Cardoza	Dent
Bilbray	Carnahan	Diaz-Balart, L.
Bilirakis	Carson	Diaz-Balart, M.
Bishop (GA)	Carter	Dicks
Bishop (NY)	Castor	Dingell
Bishop (UT)	Chabot	Doggett
Blackburn	Chandler	Donnelly
Blumenauer	Christensen	Doolittle
Blunt	Clarke	Doyle
Boehner	Clay	Drake
Bonner	Cleaver	Dreier
Bono	Clyburn	Duncan
Boozman	Coble	Edwards
Bordallo	Cohen	Ehlers
Boren	Cole (OK)	Ellison
Boswell	Conaway	Ellsworth
Boucher		Emanuel

Emerson
Engel
English (PA)
Eshoo
Etheridge
Everett
Faleomavaega
Fallin
Farr
Fattah
Feeney
Ferguson
Filner
Flake
Forbes
Fortenberry
Fortuño
Fossella
Foxx
Frank (MA)
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Giffords
Gillibrand
Gingrey
Gohmert
Gonzalez
Goode
Goodlatte
Gordon
Granger
Graves
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Hare
Harman
Hastert
Hastings (FL)
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Herseth Sandlin
Higgins
Hill
Hinchey
Hinojosa
Hirono
Hobson
Hodes
Hoekstra
Holden
Holt
Honda
Hooley
Hoyer
Hulshof
Hunter
Inglis (SC)
Inslee
Israel
Issa
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson (IL)
Johnson, E. B.
Jones (NC)
Jones (OH)
Jordan
Kagen
Kanjorski
Kaptur
Keller
Kennedy
Kildee
Kilpatrick
Kind
King (IA)
King (NY)
Kingston
Kirk
Klein (FL)
Kline (MN)
Knollenberg
Kucinich
Kuhl (NY)
LaHood
Lamborn
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lucas
Lungren, Daniel E.
Lynch
Mack
Mahoney (FL)
Maloney (NY)
Manzullo
Marchant
Markey
Marshall
Matheson
Matsui
McCarthy (CA)
McCarthy (NY)
McCaul (TX)
McCollum (MN)
McCotter
McCrery
McDermott
McGovern
McHenry
McHugh
McIntyre
McKeon
McMorris Rodgers
McNerney
McNulty
Meek (FL)
Melancon
Mica
Michaud
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murphy, Tim
Murtha
Musgrave
Myrick
Nadler
Napolitano
Neal (MA)
Neugebauer
Norton
Nunes
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Paul
Payne
Pearce
Pence
Perlmutter
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Pomeroy
Porter
Price (GA)
Price (NC)
Pryce (OH)
Putnam
Radanovich
Rahall
Ramstad
Rangel
Regula
Rehberg
Reichert
Renzi
Reyes
Reynolds
Richardson
Rodriguez
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Ross
Rothman
Roybal-Allard
Royce
Ruppersberger
Rush
Ryan (OH)
Ryan (WI)
Salazar
Sali
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Saxton
Schakowsky
Schiff
Schmidt
Schwartz
Scott (GA)
Scott (VA)
Sensenbrenner
Sessions
Sestak
Shadegg
Shays
Shea-Porter
Sherman
Shimkus
Shuler
Shuster
Simpson
Sires
Skelton
Slaughter
Smith (NE)
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Solis
Souder
Space
Spratt
Stark
Stearns
Stupak
Sullivan
Sutton
Tancredo
Tanner
Tauscher
Taylor
Terry
Thompson (CA)
Thompson (MS)
Thornberry
Tiahrt
Tiberi
Tierney
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Van Hollen
Velázquez
Visclosky
Walberg
Walden (OR)
Walsh (NY)
Walz (MN)
Wamp
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Weldon (FL)
Weller
Westmoreland
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (OH)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Yarmuth
Young (AK)
Young (FL)

NOES—1

Castle

NOT VOTING—10

Allen
Carney
Cubin
Davis, Jo Ann
Gilchrest
Jindal
Johnson (GA)
Johnson, Sam
Meeks (NY)
Serrano

□ 1407

Mrs. BACHMANN, Messrs. SIMPSON, EHLERS, BURGESS, BRADY of Texas and Mrs. BLACKBURN changed their vote from ''no'' to ''aye.''

So the amendment was agreed to.

The result of the vote was announced as above recorded.

AMENDMENT NO. 2 OFFERED BY MR. PEARCE

The CHAIRMAN. The unfinished business is the demand for a recorded vote on the amendment offered by the gentleman from New Mexico (Mr. PEARCE) on which further proceedings were postponed and on which the noes prevailed by voice vote.

The Clerk will redesignate the amendment.

The Clerk redesignated the amendment.

RECORDED VOTE

The CHAIRMAN. A recorded vote has been demanded.

A recorded vote was ordered.

The CHAIRMAN. This will be a 5-minute vote.

The vote was taken by electronic device, and there were—ayes 194, noes 230, not voting 13, as follows:

[Roll No. 882]

AYES—194

Aderholt
Akin
Alexander
Bachmann
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Barton (TX)
Bean
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono
Boozman
Boustany
Brady (TX)
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Cantor
Capito
Carter
Castle
Chabot
Coble
Cole (OK)
Conaway
Crenshaw
Culberson
Davis (KY)
Davis, David
Deal (GA)
DeFazio
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Donnelly
Doolittle
Drake
Dreier
Duncan
Ehlers
Emerson
English (PA)
Everett
Fallin
Feeney
Flake
Forbes
Fortenberry
Fortuño
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gingrey
Gohmert
Goode
Goodlatte
Granger
Graves
Hall (TX)
Hastert
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Hill
Hobson
Hoekstra
Hulshof
Hunter
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jones (NC)
Jordan
Keller
King (IA)
Kingston
Kline (MN)
Knollenberg
LaHood
Lamborn
Latham
LaTourette
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marshall
McCarthy (CA)
McCotter
McCrery
McHenry
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Mitchell
Moran (KS)
Murphy, Tim
Musgrave
Myrick
Neugebauer
Nunes
Paul
Pearce
Pence
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Porter
Price (GA)
Pryce (OH)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Sali
Saxton
Schmidt
Sensenbrenner
Sessions
Shadegg
Shimkus
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Souder
Stearns
Sullivan
Taylor
Terry
Thornberry
Tiahrt
Tiberi
Tierney
Turner
Udall (CO)
Upton
Walberg
Walden (OR)
Wamp
Weldon (FL)
Weller
Westmoreland
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)
Young (FL)

NOES—230

Abercrombie
Ackerman
Altmire
Andrews
Arcuri
Baca
Baird
Baldwin
Barrow
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Bordallo
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown, Corrine
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Christensen
Clarke
Clay
Cleaver
Clyburn
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis, Lincoln
Davis, Tom
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Engel
Eshoo
Etheridge
Faleomavaega
Farr
Fattah
Ferguson
Filner
Fossella
Frank (MA)
Giffords
Gillibrand
Gonzalez
Gordon
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick
Kind
King (NY)
Kirk
Klein (FL)
Kucinich
Kuhl (NY)
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McDermott
McGovern
McHugh
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murtha
Nadler
Napolitano
Neal (MA)
Norton
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Payne
Perlmutter
Peterson (MN)
Pomeroy
Price (NC)
Rahall
Rangel
Reyes
Reynolds
Richardson
Rodriguez
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schwartz
Scott (GA)
Scott (VA)
Sestak
Shays
Shea-Porter
Sherman
Shuler
Sires
Skelton
Slaughter
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stupak
Sutton
Tanner
Tauscher
Thompson (CA)
Thompson (MS)
Towns
Udall (NM)
Van Hollen
Velázquez
Visclosky
Walsh (NY)
Walz (MN)
Wasserman Schultz
Waters

Watson	Welch (VT)	Wu
Watt	Wexler	Wynn
Waxman	Wilson (OH)	Yarmuth
Weiner	Woolsey	

NOT VOTING—13

Allen	Hooley	Miller, George
Carney	Jindal	Serrano
Cubin	Johnson (GA)	Tancredo
Davis, Jo Ann	Marchant	
Gilchrest	McCaul (TX)	

ANNOUNCEMENT BY THE CHAIRMAN

The CHAIRMAN (during the vote). Members are advised there are 2 minutes left in this vote.

□ 1414

So the amendment was rejected.

The result of the vote was announced as above recorded.

The CHAIRMAN. Under the rule, the Committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. ROSS) having assumed the chair, Mr. ISRAEL, Chairman of the Committee of the Whole House on the state of the Union, reported that that Committee, having had under consideration the bill (H.R. 2761) to extend the Terrorism Insurance Program of the Department of the Treasury, and for other purposes, pursuant to House Resolution 660, he reported the bill, as amended by that resolution, back to the House with a further amendment adopted by the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

The question is on the amendment.

The amendment was agreed to.

The SPEAKER pro tempore. The question is on the engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, and was read the third time.

MOTION TO RECOMMIT OFFERED BY MR. DREIER

Mr. DREIER. Mr. Speaker, I offer a motion to recommit.

The SPEAKER pro tempore. Is the gentleman opposed to the bill?

Mr. DREIER. Absolutely.

The SPEAKER pro tempore. The Clerk will report the motion to recommit.

The Clerk read as follows:

Mr. Dreier moves to recommit the bill, H.R. 2761, to the Committee on Financial Services with instructions to report the same to the House promptly without the changes made by the amendment printed in part A of the report of the Committee on Rules (Report No. 110–333, 110th Congress) accompanying the resolution, H. Res. 660, 110th Congress.

The SPEAKER pro tempore. The gentleman from California is recognized for 5 minutes.

Mr. DREIER. Mr. Speaker, I offer this motion to recommit to rectify what my Rules Committee colleague, the gentleman from Miami (Mr. LINCOLN DIAZ-BALART), eloquently described as an outrage.

What we have done in this measure is unprecedented, and we are undermining the goal that I think most all of us share of trying to have a responsible Federal backdrop to deal with the potential terrorist attack on our country.

Mr. Speaker, one of the things that we all know is that certainty is absolutely essential when you are dealing with the issue of insurance. Now, we know that people can't run a business without insurance, people can't hire people without insurance, they can't build without insurance. Insurance is absolutely essential. But it is critical that certainty be provided and, unfortunately, it is not being provided under this measure.

I would like to quote the letter that was sent from our friend from New York (Mr. ACKERMAN) to Speaker PELOSI when he said, ''It is our strong belief, however, that making the entire program contingent on Congress passing a second piece of legislation completely undermines the intent and desired effect of the legislation. Under this proposal, policyholders would not know for certain whether their policies would pay out in the event of an attack and insurers could be placed in the unthinkable position of either not paying out on their policies or facing insolvency. The uncertainty that this proposed solution to the PAYGO problem would cause would render the legislation almost completely useless.''

Now, Mr. Speaker, it is very, very important that that certainty be provided. Now, I have heard that there is a letter that has come from the Speaker to my friend from New York (Mr. ACKERMAN) that says this will be rectified. Well, Mr. Speaker, by passing this motion to recommit, we can guarantee that it will be rectified. We can guarantee that it will be rectified because we are in fact sending it back to the committee.

Why is it we are doing this promptly rather than forthwith? We know there are PAYGO problems that need to be addressed by this committee. The problem with what we have done is that in the name of trying to protect this poorly crafted PAYGO rule that was put into place at the beginning of the 110th Congress, we are waiving PAYGO. That is exactly what is happening here, Mr. Speaker.

So I urge my colleagues, if you in fact want a responsible Terrorism Insurance Act package, we need to recommit this bill to the committee so that they can come out with an even better work product than the one they have today.

I urge an ''aye'' vote on the motion to recommit.

Mr. FRANK of Massachusetts. Mr. Speaker, I rise in opposition to the motion to recommit.

The SPEAKER pro tempore. The gentleman from Massachusetts is recognized for 5 minutes.

Mr. FRANK of Massachusetts. First of all, of course it says ''promptly.'' Members make a choice. The purpose of this is terrorism risk insurance expires the end of this year. We are on a reasonable timetable but not one that has a lot of water in it.

Yesterday, on an important bill that goes before the Committee on Financial Services, they said ''promptly.'' So the notion is that they can make the Committee on Financial Services a revolving door and then complain when we can't get the work done when we will have to do it two and three times.

Secondly, Members on the other side, and I don't know where the gentleman from California was on this, but in Committee, before the PAYGO problem arose, while we got substantial Republican support, 14, 19 Republicans, including the ranking member, voted ''no.'' So the Republicans had taken an opposing position in the majority. The administration is in the majority against it.

And what are they telling us? That a bill that the Republicans on the whole are against doesn't do enough for the people who want the bill. This is people intervening on behalf of people who don't want their intervention.

It is true that there is some ambiguity that I hope will be resolved; but the American Insurance Association, and that is the group that, despite the Republican's argument that this can be done by the market, says no, the market can't handle it. And, in a letter signed by a former chairman of the Republican National Committee, Governor Marc Racicot, president of the AIA, they say please go ahead with the bill. And they say: We have concerns about this fix. We hope we can go forward and work on it as opposed to delaying it further.

We got a letter today from the Chamber of Commerce and the National Association of Manufacturers, the Bankers, the League of Cities, being aware of the problem and of the first cut at fixing it, that say please go forward.

Now, if the people who were expecting to be the participants in this program said, wait a minute, this can't go forward, they would be, I think, entitled to be listened to. When people who have on the whole been opposed to the whole program and who voted against it before this arose now appear to say, oh, my goodness, this poor program, you are not doing enough justice, when they want to kill it, I don't think have a lot of credibility.

So, yes, this does need some work. There are a variety of suggestions that have been made. We do have a Senate to go forward and we have a conference process.

And I will say to the Republicans, I understand their skepticism about a conference process, because when they were in the power, they didn't have any. They did a lot of backroom, okay, we will do this.

We will have a conference. I am chairman of this committee. I can promise, and I have talked to the leadership, we will have an open conference and there will be debates and discussions.

I am explaining it because the Republicans, some of them, the newer ones don't know what one is. It will be the

House and the Senate, and we will talk about it. And so we will address this particular issue.

And, again, all of those who are in favor of this program as it was drafted, all of them want us to go forward as we continue to make this final fix. Most of those who are saying, oh, no, you can't go forward, it is not perfect, didn't like it in any case.

Mr. DREIER. Mr. Speaker, will the gentleman yield?

Mr. FRANK of Massachusetts. I yield to the gentleman from California.

Mr. DREIER. I thank my friend for yielding. Just to answer the question that was raised earlier, I will say to my friend, if we pass this motion to recommit, I will vote in favor of the legislation and I would recommend that some of the other committee follow the example set.

Mr. FRANK of Massachusetts. I thank the gentleman, but I take back my time. He will vote in favor of the legislation after it is sent back to committee, after it is wide open again to an amendment process, after members of the committee on his side of the aisle will offer a whole lot of new amendments. And so weeks could go by before we are able to get floor time again and do it. There are a lot of things on the floor, and they are complaining that we didn't pass other things.

So the gentleman will vote for it in the sweet by-and-by if we send it back. There is an alternative: We go through the regular process. The Senate votes on this, aware of the CBO. We go to an open conference. We debate it, and we bring that to the floor.

I will yield again to the gentleman.

Mr. DREIER. I thank my friend for yielding.

And I will simply say, Mr. Speaker, that the issue here happens to be jurisdictional as well. He is talking about conference committees and everything. The Rules Committee abdicates this responsibility through expedited procedures by going through this process.

Mr. FRANK of Massachusetts. I know turf is more important to some Members than anything else.

Mr. DREIER. No, the institution is very important.

Mr. FRANK of Massachusetts. It is rather odd to proclaim yourself an institutionalist while violating the rules.

The fact is that I understand turf makes some people jittery. And I will certainly advocate that the Rules Committee be included in the conference report.

Again, the Republicans have forgotten how conferences work. Conferences can have more than one committee, so the Rules Committee can get representation on the conference.

Again, everybody who is for this bill in the House and the private sector, people on the whole and the cities, the representatives of the public affected, want us to go forward and say, in good faith work, this out.

People who have been on the whole opposed to it, not entirely but on the whole opposed to it, have found this hook to try and hold it up. I don't think they are trying to hold it up to make it better when a majority of them wanted to kill it in the first place.

The SPEAKER pro tempore. Without objection, the previous question is ordered on the motion to recommit.

There was no objection.

The SPEAKER pro tempore. The question is on the motion to recommit.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

RECORDED VOTE

Mr. DREIER. Mr. Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. Pursuant to clause 9 of rule XX, the Chair will reduce to 5 minutes the minimum time for any electronic vote on the question of passage.

The vote was taken by electronic device, and there were—ayes 196, noes 228, not voting 8, as follows:

[Roll No. 883]

YEAS—196

Aderholt
Akin
Alexander
Altmire
Bachmann
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Barton (TX)
Biggert
Bilbray
Bilirakis
Bishop (UT)
Blackburn
Blunt
Boehner
Bonner
Bono
Boozman
Boustany
Brady (TX)
Broun (GA)
Brown (SC)
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Cantor
Capito
Carter
Castle
Chabot
Coble
Cole (OK)
Conaway
Crenshaw
Culberson
Davis (KY)
Davis, David
Davis, Tom
Deal (GA)
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Doolittle
Drake
Dreier
Duncan
Ehlers
Emerson
English (PA)
Everett
Fallin
Feeney
Ferguson
Flake
Forbes
Fortenberry
Foxx
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Gilchrest
Gingrey
Gohmert
Goode
Goodlatte
Granger
Graves
Hall (TX)
Hastert
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Hobson
Hoekstra
Hulshof
Hunter
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jones (NC)
Jordan
Keller
King (IA)
Kingston
Kirk
Kline (MN)
Knollenberg
Kuhl (NY)
LaHood
Lamborn
Lampson
Latham
LaTourette
Lewis (CA)
Lewis (KY)
Linder
LoBiondo
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
McCarthy (CA)
McCaul (TX)
McCotter
McCrery
McHenry
McKeon
McMorris Rodgers
Mica
Miller (FL)
Miller (MI)
Miller, Gary
Moran (KS)
Murphy, Tim
Musgrave
Myrick
Neugebauer
Nunes
Paul
Pearce
Pence
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Porter
Price (GA)
Pryce (OH)
Putnam
Radanovich
Ramstad
Regula
Rehberg
Reichert
Renzi
Reynolds
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Royce
Ryan (WI)
Sali
Saxton
Schmidt
Sensenbrenner
Sessions
Shadegg
Shimkus
Shuster
Simpson
Smith (NE)
Smith (NJ)
Smith (TX)
Souder
Stearns
Sullivan
Tancredo
Terry
Thornberry
Tiahrt
Tiberi
Turner
Upton
Walberg
Walden (OR)
Walsh (NY)
Wamp
Weldon (FL)
Weller
Westmoreland
Whitfield
Wicker
Wilson (NM)
Wilson (SC)
Wolf
Young (AK)
Young (FL)

NAYS—228

Abercrombie
Ackerman
Andrews
Arcuri
Baca
Baird
Baldwin
Barrow
Bean
Becerra
Berkley
Berman
Berry
Bishop (GA)
Bishop (NY)
Blumenauer
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown, Corrine
Butterfield
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Clarke
Clay
Cleaver
Clyburn
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis, Lincoln
DeFazio
DeGette
Delahunt
DeLauro
Dicks
Dingell
Doggett
Donnelly
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Engel
Eshoo
Etheridge
Farr
Fattah
Filner
Fossella
Frank (MA)
Giffords
Gillibrand
Gonzalez
Gordon
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hare
Harman
Hastings (FL)
Herseth Sandlin
Higgins
Hill
Hinchey
Hinojosa
Hirono
Hodes
Holden
Holt
Honda
Hooley
Hoyer
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (OH)
Kagen
Kanjorski
Kaptur
Kennedy
Kildee
Kilpatrick
Kind
King (NY)
Klein (FL)
Kucinich
Langevin
Lantos
Larsen (WA)
Larson (CT)
Lee
Levin
Lewis (GA)
Lipinski
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Marshall
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McDermott
McGovern
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Michaud
Miller (NC)
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murtha
Nadler
Napolitano
Neal (MA)
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Payne
Perlmutter
Peterson (MN)
Pomeroy
Price (NC)
Rahall
Rangel
Reyes
Richardson
Rodriguez
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Schakowsky
Schiff
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sestak
Shays
Shea-Porter
Sherman
Shuler
Sires
Skelton
Slaughter
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stupak
Sutton
Tanner
Tauscher
Taylor
Thompson (CA)
Thompson (MS)
Tierney
Towns
Udall (CO)
Udall (NM)
Van Hollen
Velázquez
Visclosky
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Wexler
Wilson (OH)
Woolsey
Wu
Wynn
Yarmuth

NOT VOTING—8

Allen
Carney
Cubin
Davis, Jo Ann
Jindal
Johnson (GA)
McHugh
Miller, George

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised there are 2 minutes remaining on this vote.

□ 1445

Mr. RUPPERSBERGER changed his vote from ''yea'' to ''nay.''

So the motion to recommit was rejected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. PRICE of Georgia. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 312, nays 110, not voting 10, as follows:

[Roll No. 884]

YEAS—312

Abercrombie
Ackerman
Alexander
Altmire
Andrews
Arcuri
Baca
Baird
Baldwin
Barrow
Bean
Becerra
Berkley
Berman
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blumenauer
Blunt
Bono
Boozman
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Butterfield
Calvert
Cantor
Capito
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Clarke
Clay
Cleaver
Clyburn
Coble
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crenshaw
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis (KY)
Davis, Lincoln
Davis, Tom
DeFazio
DeGette
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Donnelly
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Emerson
Engel
English (PA)
Eshoo
Etheridge
Farr
Fattah
Ferguson
Filner
Fortenberry
Fossella
Frank (MA)
Frelinghuysen
Gallegly
Gerlach
Giffords
Gilchrest
Gillibrand
Gonzalez
Gordon
Graves
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Hare
Harman
Hastert
Hastings (FL)
Hayes
Herseth Sandlin
Higgins
Hill
Hinchey
Hinojosa
Hirono
Hobson
Hodes
Holden
Holt
Honda
Hooley
Hoyer
Hulshof
Hunter
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (NC)
Jones (OH)
Kagen
Kanjorski
Kaptur
Keller
Kennedy
Kildee
Kilpatrick
Kind
King (NY)
Kirk
Klein (FL)
Knollenberg
Kucinich
Kuhl (NY)
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Lee
Levin
Lewis (GA)
Lewis (KY)
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McCotter
McDermott
McGovern
McHenry
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Mica
Michaud
Miller (MI)
Miller (NC)
Miller, Gary
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murphy, Tim
Murtha
Nadler
Napolitano
Neal (MA)
Nunes
Oberstar
Obey
Olver
Ortiz
Pallone
Pascrell
Pastor
Payne
Perlmutter
Peterson (MN)
Pickering
Platts
Pomeroy
Porter
Price (NC)
Pryce (OH)
Putnam
Rahall
Ramstad
Rangel
Regula
Rehberg
Reichert
Renzi
Reyes
Reynolds
Richardson
Rodriguez
Rogers (KY)
Rogers (MI)
Ros-Lehtinen
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Saxton
Schakowsky
Schiff
Schmidt
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sessions
Sestak
Shays
Shea-Porter
Sherman
Shimkus
Shuler
Sires
Skelton
Slaughter
Smith (NJ)
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stearns
Stupak
Sutton
Tanner
Tauscher
Taylor
Terry
Thompson (CA)
Thompson (MS)
Thornberry
Tiahrt
Tiberi
Tierney
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Van Hollen
Velázquez
Visclosky
Walberg
Walsh (NY)
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Weller
Wexler
Whitfield
Wilson (NM)
Wilson (OH)
Wolf
Woolsey
Wu
Wynn
Yarmuth
Young (AK)
Young (FL)

NAYS—110

Aderholt
Akin
Bachmann
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Barton (TX)
Berry
Biggert
Bilbray
Blackburn
Bonner
Boustany
Brady (TX)
Broun (GA)
Burgess
Burton (IN)
Buyer
Camp (MI)
Campbell (CA)
Cannon
Carter
Castle
Chabot
Cole (OK)
Conaway
Culberson
Davis, David
Deal (GA)
Doolittle
Drake
Dreier
Duncan
Ehlers
Everett
Fallin
Feeney
Flake
Forbes
Foxx
Franks (AZ)
Garrett (NJ)
Gingrey
Gohmert
Goode
Goodlatte
Granger
Hastings (WA)
Heller
Hensarling
Herger
Hoekstra
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jordan
King (IA)
Kingston
Kline (MN)
LaHood
Lamborn
Lewis (CA)
Linder
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
Marshall
McCarthy (CA)
McCaul (TX)
McCrery
McKeon
McMorris Rodgers
Miller (FL)
Musgrave
Myrick
Neugebauer
Paul
Pearce
Pence
Peterson (PA)
Petri
Pitts
Poe
Price (GA)
Radanovich
Rogers (AL)
Rohrabacher
Roskam
Royce
Ryan (WI)
Sali
Sensenbrenner
Shadegg
Shuster
Simpson
Smith (NE)
Smith (TX)
Souder
Sullivan
Tancredo
Walden (OR)
Wamp
Weldon (FL)
Westmoreland
Wicker
Wilson (SC)

NOT VOTING—10

Allen
Boehner
Carney
Cubin
Davis, Jo Ann
Delahunt
Jindal
Johnson (GA)
McHugh
Miller, George

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised that 2 minutes are remaining in this vote.

□ 1454

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

AUTHORIZING THE CLERK TO MAKE CORRECTIONS IN ENGROSSMENT OF H.R. 2761, TERRORISM RISK INSURANCE REVISION AND EXTENSION ACT OF 2007

Mr. FRANK of Massachusetts. Mr. Speaker, I ask unanimous consent that in the engrossment of H.R. 2761, the Clerk be authorized to correct section numbers, punctuation, cross-references, and to make such other technical and conforming changes as may be necessary to accurately reflect the actions of the House.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 1644

Mr. ANDREWS. Mr. Speaker, I ask unanimous consent that the gentleman from Wisconsin's (Mr. RYAN) name be removed as a cosponsor of H.R. 1644. Our staff inadvertently, mistakenly added his name.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote is objected to under clause 6 of rule XX.

Record votes on postponed questions will be taken later today.

FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007

Mr. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3580) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3580

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Amendments Act of 2007''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

SEC. 101. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2007''.

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the matter before paragraph (1), by striking ''For purposes of this subchapter'' and inserting ''For purposes of this part'';

(2) in paragraph (1)—

(A) in subparagraph (A), by striking ''505(b)(1),'' and inserting ''505(b), or'';

(B) by striking subparagraph (B);

(C) by redesignating subparagraph (C) as subparagraph (B); and

(D) in the matter following subparagraph (B), as so redesignated, by striking ''subparagraph (C)'' and inserting ''subparagraph (B)'';

(3) in paragraph (3)(C)—

(A) by striking ''505(j)(7)(A)'' and inserting ''505(j)(7)(A) (not including the discontinued section of such list)''; and

(B) by inserting before the period ''(not including the discontinued section of such list)'';

(4) in paragraph (4), by inserting before the period at the end the following: ''(such as capsules, tablets, or lyophilized products before reconstitution)'';

(5) by amending paragraph (6)(F) to read as follows:

''(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

''(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

''(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

''(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and

clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

''(v) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).'';

(6) in paragraph (8)—

(A) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(B) by striking ''April 1997'' and inserting ''October 1996'';

(7) by redesignating paragraph (9) as paragraph (11); and

(8) by inserting after paragraph (8) the following paragraphs:

''(9) The term 'person' includes an affiliate thereof.

''(10) The term 'active', with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''2003'' and inserting ''2008'';

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting ''OR WITHDRAWN BEFORE FILING'' after ''REFUSED FOR FILING''; and

(ii) by inserting before the period at the end the following: ''or withdrawn without a waiver before filing'';

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

''(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).''; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(B) by adding at the end the following:

''(C) SPECIAL RULES FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

''(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

''(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

''(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

''(iii) DEFINITION.—For purposes of this subparagraph, the term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.''.

(b) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—For each of the fiscal years 2008 through 2012, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

''(A) $392,783,000; and

''(B) an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).

''(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

''(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

''(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

''(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

''(3) MODIFIED WORKLOAD ADJUSTMENT FACTOR FOR FISCAL YEAR 2007.—For purposes of paragraph (1)(B), the Secretary shall determine the modified workload adjustment factor by determining the dollar amount that results from applying the methodology that was in effect under subsection (c)(2) for fiscal year 2007 to the amount $354,893,000, except that, with respect to the portion of such determination that is based on the change in the total number of commercial investigational new drug applications, the Secretary shall count the number of such applications that were active during the most recent 12-month period for which data on such submissions is available.

''(4) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

''(A) IN GENERAL.—For each of the fiscal years 2008 through 2012, paragraph (1)(A) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

''(B) AMOUNT DETERMINED.—For each of the fiscal years 2008 through 2012, the amount determined under this subparagraph is the sum of—

''(i) $392,783,000; plus

''(ii)(I) for fiscal year 2008, $25,000,000;

''(II) for fiscal year 2009, $35,000,000;

''(III) for fiscal year 2010, $45,000,000;

''(IV) for fiscal year 2011, $55,000,000; and

''(V) for fiscal year 2012, $65,000,000.''.

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A), by striking ''The revenues established in subsection (b)'' and inserting ''For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)'';

(B) in subparagraph (A), by striking ''or'' at the end;

(C) in subparagraph (B), by striking the period at the end and inserting '', or'';

(D) by inserting after subparagraph (B) the following:

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 years of the preceding 6 fiscal years.''; and

(E) in the matter following subparagraph (C) (as added by subparagraph (D)), by striking ''fiscal year 2003'' and inserting ''fiscal year 2008''.

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A), by striking ''Beginning with fiscal year 2004,'' and inserting ''For fiscal year 2009 and subsequent fiscal years,'';

(B) in subparagraph (A), in the first sentence—

(i) by striking ''human drug applications,'' and inserting ''human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph),'';

(ii) by striking ''commercial investigational new drug applications,''; and

(iii) by inserting before the period the following: '', and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available'';

(C) in subparagraph (B), by adding at the end the following: ''Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.''; and

(D) by adding at the end the following:

''(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees and revenue amounts for fiscal year 2009 and to make recommendations, if warranted, for future changes in the methodology for calculating the adjustment. After review of the recommendations, the Secretary shall, if warranted, make appropriate changes to the methodology, and the changes shall be effective for each of the fiscal years 2010 through 2012. The Secretary shall not make any adjustment for changes in review activities for any fiscal year after 2009 unless such study has been completed.''.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, before making adjustments under paragraphs (1) and (2), decrease the fee revenue amount established in subsection (b) if actual costs paid for rent and rent-related expenses for the preceding fiscal year are less than estimates made for such year in fiscal year 2006. Any reduction made under this paragraph shall not exceed the amount by which such costs fall below the estimates made in fiscal year 2006 for such fiscal year, and shall not exceed $11,721,000 for any fiscal year.''.

(4) FINAL YEAR ADJUSTMENT.—Paragraph (4) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended to read as follows:

''(4) FINAL YEAR ADJUSTMENT.—

''(A) INCREASE IN FEES.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2013. If such an adjustment is necessary, the rationale for the amount of the increase

shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2012. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

''(B) DECREASE IN FEES.—

''(i) IN GENERAL.—For fiscal year 2012, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1), (2), and (3), decrease the fee revenues and fees established in subsection (b) by the amount determined in clause (ii), if, for fiscal year 2009 or 2010—

''(I) the amount of the total appropriations for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriations for the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1); and

''(II) the amount of the total appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations expended for the process for the review of human drug applications at the Food and Drug Administration for fiscal year 2008 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under paragraph (1).

''(ii) AMOUNT OF DECREASE.—The amount determined in this clause is the lesser of—

''(I) the amount equal to the sum of the amounts that, for each of fiscal years 2009 and 2010, is the lesser of—

''(aa) the excess amount described in clause (i)(II) for such fiscal year; or

''(bb) the amount specified in subsection (b)(4)(B)(ii) for such fiscal year; or

''(II) $65,000,000.

''(iii) LIMITATIONS.—

''(I) FISCAL YEAR CONDITION.—In making the determination under clause (ii), an amount described in subclause (I) of such clause for fiscal year 2009 or 2010 shall be taken into account only if subclauses (I) and (II) of clause (i) apply to such fiscal year.

''(II) RELATION TO SUBPARAGRAPH (A).—The Secretary shall limit any decrease under this paragraph if such a limitation is necessary to provide for the 3 months of operating reserves described in subparagraph (A).''.

(5) LIMIT.—Paragraph (5) of section 736(c) (21 U.S.C. 379h(c)), as redesignated by paragraph (3)(A), is amended by striking ''2002'' and inserting ''2007''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A)—

(A) by inserting after ''The Secretary shall grant'' the following: ''to a person who is named as the applicant in a human drug application''; and

(B) by inserting ''to that person'' after ''one or more fees assessed'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(3) by inserting after paragraph (1) the following:

''(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.''; and

(4) in paragraph (4) (as redesignated by paragraph (2)), in subparagraph (A), by inserting before the period the following: '', and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce''.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4) of this subsection.''.

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

''(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2008 through 2010 and the amount of fees estimated to be collected under this section for fiscal year 2011 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2008 through 2011, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

(f) EXEMPTION FOR ORPHAN DRUGS.—Section 736 (21 U.S.C. 379h) is further amended by adding at the end the following:

''(k) ORPHAN DRUGS.—

''(1) EXEMPTION.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act shall be exempt from product and establishment fees under this section, if the drug meets all of the following conditions:

''(A) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for product and establishment fees.

''(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year.

''(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.''.

(g) CONFORMING AMENDMENT.—Section 736(a) (21 U.S.C. 379h(a)) is amended in paragraphs (1)(A)(i), (1)(A)(ii), (2)(A), and (3)(A) by striking ''(c)(4)'' each place such term appears and inserting ''(c)(5)''.

(h) TECHNICAL AMENDMENT.—

(1) AMENDMENT.—Section 736(g)(1) (21 U.S.C. 379h(g)(1)) is amended by striking the first sentence and inserting the following: ''Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.''.

(2) EFFECTIVE DATE.—Paragraph (1) shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188; 116 Stat. 687).

SEC. 104. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following:

''SEC. 736A. FEES RELATING TO ADVISORY REVIEW OF PRESCRIPTION-DRUG TELEVISION ADVERTISING.

''(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ADVISORY REVIEW FEE.—

''(A) IN GENERAL.—With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a 'DTC advertisement'), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

''(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

''(C) NOTICE TO SECRETARY OF NUMBER OF ADVERTISEMENTS.—Not later than June 1 of each fiscal year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

''(D) PAYMENT.—

''(i) IN GENERAL.—The fee required by subparagraph (A) (referred to in this section as 'an advisory review fee') shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after the date of the enactment of the Food and Drug Administration Amendments of 2007 or an earlier date as specified by the Secretary.

''(ii) EFFECT OF SUBMISSION.—Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

''(iii) NOTICE REGARDING CARRYOVER SUBMISSIONS.—In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

''(E) MODIFICATION OF ADVISORY REVIEW FEE.—

''(i) LATE PAYMENT.—If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary), the fees

shall be regarded as late and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

''(ii) EXCEEDING IDENTIFIED NUMBER OF SUBMISSIONS.—If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

''(F) LIMITS.—

''(i) SUBMISSIONS.—For each advisory review fee paid by a person for a fiscal year, the person is entitled to acceptance for advisory review by the Secretary of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

''(ii) NO REFUNDS.—Except as provided by subsections (d)(4) and (f), fees paid under this section shall not be refunded.

''(iii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

''(iv) RIGHT TO ADVISORY REVIEW NOT TRANSFERABLE.—The right to an advisory review under this paragraph is not transferable, except to a successor in interest.

''(2) OPERATING RESERVE FEE.—

''(A) IN GENERAL.—Each person that on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to fee established under subsection (d)(2) (referred to in this section as an 'operating reserve fee') for the first fiscal year in which an advisory review fee is assessed to such person. The person is not subject to an operating reserve fee for any other fiscal year.

''(B) PAYMENT.—Except as provided in subparagraph (C), the operating reserve fee shall be due no later than—

''(i) October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1); or

''(ii) for fiscal year 2008, 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary.

''(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the program under this section, that person submits any DTC advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (a)(1)(C), that person shall pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(E)(ii). Fees required by this subparagraph shall be in addition to any fees required by subparagraph (A). Fees under this subparagraph shall be due 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

''(D) LATE PAYMENT.—

''(i) IN GENERAL.—Notwithstanding subparagraph (B), and subject to clause (ii), an operating reserve fee shall be regarded as late if the person required to pay the fee has not paid the complete operating reserve fee by—

''(I) for fiscal year 2008, 150 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 or an earlier date specified by the Secretary; or

''(II) in any subsequent year, November 1.

''(ii) COMPLETE PAYMENT.—The complete operating reserve fee shall be due and payable 20 days before any DTC advertisement is submitted by such person to the Secretary for advisory review.

''(iii) AMOUNT.—Notwithstanding any other provision of this section, an operating reserve fee that is regarded as late under this subparagraph shall be equal to 150 percent of the operating reserve fee that otherwise would have applied pursuant to subsection (d).

''(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsections (c) and (g)(4).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; U.S. city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of DTC advertisements for advisory review prior to initial dissemination. With respect to such adjustment:

''(A) The adjustment shall be determined by the Secretary based upon the number of DTC advertisements identified pursuant to subsection (a)(1)(C) for the upcoming fiscal year, excluding allowable previously paid carry over submissions. The adjustment shall be determined by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)). The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

''(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

''(3) ANNUAL FEE SETTING FOR ADVISORY REVIEW.—

''(A) IN GENERAL.—Not later than August 1 of each fiscal year (or, with respect to fiscal year 2008, not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007), the Secretary shall establish for the next fiscal year the DTC advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under paragraphs (1) and (2), and the number of DTC advertisements identified pursuant to subsection (a)(1)(C), excluding allowable previously-paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of DTC advertisements so identified, excluding allowable previously-paid carry over submissions under subsection (a)(1)(F)(i).

''(B) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for fiscal year 2008 may not be more than $83,000 per submission for advisory review.

''(C) ANNUAL FEE LIMIT.—Notwithstanding subsection (b) and the adjustments pursuant to this subsection, the fee established under subparagraph (A) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

''(D) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

''(d) OPERATING RESERVES.—

''(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the program under this section in the event the fees collected in any subsequent fiscal year pursuant to subsection (a)(1) do not generate the fee revenue amount established for that fiscal year.

''(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of DTC advertisements identified by that person pursuant to subsection (a)(1)(C) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year, except that in no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the program under this section in fiscal year 2008.

''(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsections (b) and (c) and the amount of fees actually collected for that fiscal year pursuant to subsection (a)(1), or to pay costs of ending the program under this section if it is terminated pursuant to subsection (f) or not reauthorized beyond fiscal year 2012.

''(4) REFUND OF OPERATING RESERVES.—Within 120 days after the end of fiscal year 2012, or if the program under this section ends early pursuant to subsection (f), the

Secretary, after setting aside sufficient operating reserve amounts to terminate the program under this section, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

''(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other requirement, a submission for advisory review of a DTC advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

''(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

''(1) INITIAL FUNDING.—If on November 1, 2007, or 120 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, whichever is later, the Secretary has not received at least $11,250,000 in advisory review fees and operating reserve fees combined, the program under this section shall not commence and all collected fees shall be refunded.

''(2) LATER FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of the fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below $9,000,000, adjusted for inflation (as described in subsection (c)(1)), the program under this section shall terminate, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and finally, unused advisory review fees from the relevant fiscal year.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

''(ii) shall be available for obligation only if the amounts appropriated as budget authority for such fiscal year are sufficient to support a number of full-time equivalent review employees that is not fewer than the number of such employees supported in fiscal year 2007.

''(B) REVIEW EMPLOYEES.—For purposes of subparagraph (A)(ii), the term 'full-time equivalent review employees' means the total combined number of full-time equivalent employees in—

''(i) the Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Food and Drug Administration; and

''(ii) the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, Food and Drug Administration.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2008 through 2012, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted pursuant to subsection (c) and paragraph (4) of this subsection, plus amounts collected for the reserve fund under subsection (d).

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'advisory review' means reviewing and providing advisory comments on DTC advertisements regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

''(2) The term 'advisory review fee' has the meaning indicated for such term in subsection (a)(1)(D).

''(3) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in one fiscal year that is submitted for review in the following fiscal year.

''(4) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product (as defined in section 735(3)) intended to be displayed on any television channel for less than 3 minutes.

''(5) The term 'DTC advertisement' has the meaning indicated for such term in subsection (a)(1)(A).

''(6) The term 'operating reserve fee' has the meaning indicated for such term in subsection (a)(2)(A).

''(7) The term 'person' includes an individual, partnership, corporation, and association, and any affiliate thereof or successor in interest.

''(8) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on DTC advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the program under this section that are not necessary for the advisory review of DTC advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

''(9) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

''(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

''(E) terminating the program under this section pursuant to subsection (f)(2) if that becomes necessary.

''(10) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

''(11) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.''.

SEC. 105. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 2 of subchapter C of chapter VII (21 U.S.C. 379g et seq.), as amended by section 104, is further amended by inserting after section 736A the following:

''SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

''(b) FISCAL REPORT.—Beginning with fiscal year 2008, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

''(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

''(D) publish the comments on the Food and Drug Administration's Internet Web site.

''(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

''(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 106. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by sections 102, 103, and 104 cease to be effective October 1, 2012.

(b) REPORTING REQUIREMENTS.—The amendment made by section 105 ceases to be effective January 31, 2013.

SEC. 107. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2007, regardless of the date of the enactment of this Act.

SEC. 108. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 109. TECHNICAL AMENDMENT; CONFORMING AMENDMENT.

(a) Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1) by striking ''subchapter'' and inserting ''part''.

(b) Paragraph (11) of section 739 (21 U.S.C. 379j–11) is amended by striking ''735(9)'' and inserting ''735(11)''.

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2007

SEC. 201. SHORT TITLE; REFERENCES IN TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2007''.

(b) REFERENCES IN TITLE.—Except as otherwise specified, amendments made by this title to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

Subtitle A—Fees Related to Medical Devices

SEC. 211. DEFINITIONS.

Section 737 is amended—

(1) in the matter preceding paragraph (1), by striking ''For purposes of this subchapter'' and inserting ''For purposes of this part'';

(2) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (8), (9), (10), and (12), respectively;

(3) by inserting after paragraph (4) the following:

''(5) The term '30-day notice' means a notice under section 515(d)(6) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

''(6) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

''(7) The term 'annual fee', for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.'';

(4) in paragraph (10), as so redesignated—

(A) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(B) by striking ''April 2002'' and inserting ''October 2001'';

(5) by inserting after paragraph (10), as so amended, the following:

''(11) The term 'person' includes an affiliate thereof.''; and

(6) by inserting after paragraph (12), as so redesignated, the following:

''(13) The term 'establishment subject to a registration fee' means an establishment that is required to register with the Secretary under section 510 and is one of the following types of establishments:

''(A) MANUFACTURER.—An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

''(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that, within the meaning of section 201(ll)(2)(A), performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.

''(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.''.

SEC. 212. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(A) in paragraph (1), by striking ''Beginning on the date of the enactment of the Medical Device User Fee and Modernization Act of 2002'' and inserting ''Beginning in fiscal year 2008''; and

(B) by amending the designation and heading of paragraph (2) to read as follows:

''(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—''.

(2) FEE AMOUNTS.—Section 738(a)(2)(A) (21 U.S.C. 379j(a)(2)(A)) is amended—

(A) in clause (iii), by striking ''a fee equal to the fee that applies'' and inserting ''a fee equal to 75 percent of the fee that applies'';

(B) in clause (iv), by striking ''21.5 percent'' and inserting ''15 percent'';

(C) in clause (v), by striking ''7.2 percent'' and inserting ''7 percent'';

(D) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(E) by inserting after clause (v) the following:

''(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).'';

(F) in clause (viii), as so redesignated—

(i) by striking ''1.42 percent'' and inserting ''1.84 percent''; and

(ii) by striking '', subject to any adjustment under subsection (e)(2)(C)(ii)''; and

(G) by inserting after such clause (viii) the following:

''(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

''(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).''.

(3) PAYMENT.—Section 738(a)(2)(C) (21 U.S.C. 379j(a)(2)(C)) is amended to read as follows:

''(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.''.

(4) REFUNDS.—Section 738(a)(2)(D) (21 U.S.C. 379j(a)(2)(D)) is amended—

(A) in clause (iii), by striking the last two sentences; and

(B) by adding after clause (iii) the following:

''(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

''(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

''(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.''.

(5) ANNUAL ESTABLISHMENT REGISTRATION FEE.—Section 738(a) (21 U.S.C. 379j(a)) is amended by adding after paragraph (2) the following:

''(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

''(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

''(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.''.

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration	$1,706	$1,851	$2,008	$2,179	$2,364.''.

(c) ANNUAL FEE SETTING.—

(1) IN GENERAL.—Section 738(c) (21 U.S.C. 379j(c)(1)) is amended—

(A) in the subsection heading, by striking ''Annual Fee Setting'' and inserting ''ANNUAL FEE SETTING''; and

(B) in paragraph (1), by striking the last sentence.

(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT FEE.—Section 738(c) (21 U.S.C. 379j(c)), as amended by paragraph (1), is further amended—

(A) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(B) by inserting after paragraph (1) the following:

''(2) ADJUSTMENT.—

''(A) IN GENERAL.—When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

''(B) PUBLICATION.—For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.''; and

(C) in paragraph (4), as redesignated by this paragraph, in subparagraph (A)—

(i) by striking ''For fiscal years 2006 and 2007, the Secretary'' and inserting ''The Secretary''; and

(ii) by striking ''for the first month of fiscal year 2008'' and inserting ''for the first month of the next fiscal year''.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 738(d)(1) (21 U.S.C. 379j(d)(1)) is amended—

(A) by striking '', partners, and parent firms''; and

(B) by striking ''clauses (i) through (vi) of subsection (a)(2)(A)'' and inserting ''clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)''.

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—Section 738(d)(2)(A) (21 U.S.C. 379j(d)(2)(A)) is amended by striking '', partners, and parent firms''.

(B) EVIDENCE OF QUALIFICATION.—Section 738(d)(2)(B) (21 U.S.C. 379j(d)(2)(B)) is amended—

(i) by striking ''(B) EVIDENCE OF QUALIFICATION.—An applicant'' and inserting the following:

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant'';

(ii) by striking ''The applicant shall support its claim'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim'';

(iii) by striking '', partners, and parent firms'' each place it appears;

(iv) by striking the last sentence and inserting ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(d)(2)(C) (21 U.S.C. 379j(d)(2)(C)) is amended to read as follows:

''(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

''(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or periodic reporting concerning a class III device; and

''(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.''.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—Section 738(e)(1) (21 U.S.C. 379j(e)(1)) is amended—

(A) by striking ''2004'' and inserting ''2008''; and

(B) by striking ''(a)(2)(A)(vii)'' and inserting ''(a)(2)(A)(viii)''.

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—Section 738(e)(2)(A) (21 U.S.C. 379j(e)(2)(A)) is amended by striking '', partners, and parent firms''.

(B) EVIDENCE OF QUALIFICATION.—Section 738(e)(2)(B) (21 U.S.C. 379j(e)(2)(B)) is amended—

(i) by striking ''(B) EVIDENCE OF QUALIFICATION.—An applicant'' and inserting the following:

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant'';

(ii) by striking ''The applicant shall support its claim'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim'';

(iii) by striking '', partners, and parent firms'' each place it appears;

(iv) by striking the last sentence and inserting ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.''; and

(v) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.''.

(3) REDUCED FEES.—Section 738(e)(2)(C) (21 U.S.C. 379j(e)(2)(C)) is amended to read as follows:

''(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).''.

(f) EFFECT OF FAILURE TO PAY FEES.—Section 738(f) (21 U.S.C. 379j(f)) is amended to read as follows:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device submitted by a person subject to fees under subsection (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

''(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.''.

(g) CONDITIONS.—Section 738(g) (21 U.S.C. 379j(g)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

''(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

''(B) fees were not assessed under subsection (a) for the previous fiscal year.''; and

(2) by amending paragraph (2) to read as follows:

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.''.

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 738(h)(3) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

''(3) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $48,431,000 for fiscal year 2008;

''(B) $52,547,000 for fiscal year 2009;

''(C) $57,014,000 for fiscal year 2010;

''(D) $61,860,000 for fiscal year 2011; and

''(E) $67,118,000 for fiscal year 2012.''.

(2) OFFSET.—Section 738(h)(4) (21 U.S.C. 379j(h)(3)) is amended to read as follows:

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

SEC. 213. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 3 of subchapter C of chapter VII is amended by inserting after section 738 the following:

''SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) REPORTS.—

''(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

''(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

''(b) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

''(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

''(D) publish the comments on the Food and Drug Administration's Internet Web site.

''(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

''(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any

changes made to the recommendations in response to such views and comments.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 214. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 215. ADDITIONAL AUTHORIZATION OF APPROPRIATIONS FOR POSTMARKET SAFETY INFORMATION.

For the purpose of collecting, developing, reviewing, and evaluating postmarket safety information on medical devices, there are authorized to be appropriated to the Food and Drug Administration, in addition to the amounts authorized by other provisions of law for such purpose—

(1) $7,100,000 for fiscal year 2008;

(2) $7,455,000 for fiscal year 2009;

(3) $7,827,750 for fiscal year 2010;

(4) $8,219,138 for fiscal year 2011; and

(5) $8,630,094 for fiscal year 2012.

SEC. 216. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.

SEC. 217. SUNSET CLAUSE.

The amendments made by this subtitle cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act (regarding annual performance and financial reports) ceases to be effective January 31, 2013.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 221. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2007'' and inserting ''2012''.

SEC. 222. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 360(b)) is amended—

(1) by striking ''(b) On or before'' and inserting ''(b)(1) On or before'';

(2) by striking ''or a device or devices''; and

(3) by adding at the end the following:

''(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.''.

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by striking ''On or before December 31'' and all that follows and inserting the following: ''Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

''(A) upon first engaging in any such activity, immediately register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation; and

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter—

''(i) with respect to drugs, register with the Secretary on or before December 31 of each year; and

''(ii) with respect to devices, register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.''.

SEC. 223. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Section 510(j)(2) (21 U.S.C. 360(j)(2)) is amended, in the matter preceding subparagraph (A), by striking ''Each person'' and all that follows through ''the following information:'' and inserting ''Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:''.

SEC. 224. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

''(p) Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.''.

SEC. 225. REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the appropriate use of the process under section 510(k) of the Federal Food, Drug, and Cosmetic Act as part of the device classification process to determine whether a new device is as safe and effective as a classified device.

(b) CONSIDERATION.—In determining the effectiveness of the premarket notification and classification authority under section 510(k) and subsections (f) and (i) of section 513 of the Federal Food, Drug, and Cosmetic Act, the study under subsection (a) shall consider the Secretary of Health and Human Services's evaluation of the respective intended uses and technologies of such devices, including the effectiveness of such Secretary's comparative assessment of technological characteristics such as device materials, principles of operations, and power sources.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

SEC. 226. UNIQUE DEVICE IDENTIFICATION SYSTEM.

(a) IN GENERAL.—Section 519 (21 U.S.C. 360i) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

''Unique Device Identification System

''(f) The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.''.

(b) CONFORMING AMENDMENT.—Section 303 (21 U.S.C. 333) is amended—

(1) by redesignating the subsection that follows subsection (e) as subsection (f); and

(2) in paragraph (1)(B)(ii) of subsection (f), as so redesignated, by striking ''519(f)'' and inserting ''519(g)''.

SEC. 227. FREQUENCY OF REPORTING FOR CERTAIN DEVICES.

Subparagraph (B) of section 519(a)(1) (21 U.S.C. 360i(a)(1)) is amended by striking ''were to recur;'' and inserting the following: ''were to recur, which report under this subparagraph—

''(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

''(I) a class III device;

''(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

''(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

''(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

''(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)''.

SEC. 228. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking ''Not later than one year after the date of the enactment of this subsection, the Secretary'' and inserting ''The Secretary'';

(2) in paragraph (2), by—

(A) striking ''Not later than 180 days after the date of enactment of this subsection, the Secretary'' and inserting ''The Secretary''; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

''(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

''(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).'';

(4) by amending paragraph (6) to read as follows:

''(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

''(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

''(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

''(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

''(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

''(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

''(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

''(aa) at least 1 of such devices is marketed in the United States; and

''(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

''(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

''(I) denies clearance to participate as provided under subparagraph (C); or

''(II) makes a request under clause (ii).

''(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

''(I) compliance data for the establishment in accordance with clause (iii)(I); or

''(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

''(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

''(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

''(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

''(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

''(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

''(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

''(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

''(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.'';

(5) in paragraph (7)—

(A) in subparagraph (A), by striking ''(A) Persons'' and all that follows through the end and inserting the following: ''(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.''; and

(B) by adding at the end the following:

''(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.''; and

(6) in paragraph (10)(C)(iii), by striking ''based'' and inserting ''base''.

SEC. 229. STUDY OF NOSOCOMIAL INFECTIONS RELATING TO MEDICAL DEVICES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(1) the number of nosocomial infections attributable to new and reused medical devices; and

(2) the causes of such nosocomial infections, including the following:

(A) Reprocessed single-use devices.

(B) Handling of sterilized medical devices.

(C) In-hospital sterilization of medical devices.

(D) Health care professionals' practices for patient examination and treatment.

(E) Hospital-based policies and procedures for infection control and prevention.

(F) Hospital-based practices for handling of medical waste.

(G) Other causes.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit to the Congress a report on the results of such study.

(c) DEFINITION.—In this section, the term ''nosocomial infection'' means an infection that is acquired while an individual is a patient at a hospital and was neither present nor incubating in the patient prior to receiving services in the hospital.

SEC. 230. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer'', or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing to determine consumer understanding of label warnings.

(c) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

SEC. 301. SHORT TITLE.

This title may be cited as the ''Pediatric Medical Device Safety and Improvement Act of 2007''.

SEC. 302. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

''SEC. 515A. PEDIATRIC USES OF DEVICES.

''(a) NEW DEVICES.—

''(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

''(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

''(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

''(B) the number of affected pediatric patients.

''(3) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

''(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

''(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

''(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

''(D) the review time for each device described in subparagraphs (A), (B), and (C).

''(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

''(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

''(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

''(c) PEDIATRIC SUBPOPULATION.—For purposes of this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).''.

SEC. 303. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking ''No'' and inserting ''Except as provided in paragraph (6), no'';

(2) in paragraph (5)—

(A) by inserting '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,'' after ''public health''; and

(B) by adding at the end the following: ''If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.''; and

(3) by striking paragraph (6) and inserting after paragraph (5) the following new paragraphs:

''(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

''(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

''(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of the enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

''(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

''(iv) The request for such exemption is submitted on or before October 1, 2012.

''(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

''(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

''(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

''(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

''(I) Neonates.

''(II) Infants.

''(III) Children.

''(IV) Adolescents.

''(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

''(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.''.

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions

that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of purchasing pediatric devices, based on a representative sampling of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 305, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.

(c) GUIDANCE.—Not later than 180 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 304. ENCOURAGING PEDIATRIC MEDICAL DEVICE RESEARCH.

(a) CONTACT POINT FOR AVAILABLE FUNDING.—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking ''and'' after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (22) the following:

''(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.''.

(b) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Secretary of Health and Human Services shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

(2) CONTENTS.—The plan under paragraph (1) shall include—

(A) the current status of federally funded pediatric medical device research;

(B) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(C) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 306. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting '', including increasing pediatric access to medical devices'' after ''pediatric issues''.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''and 505B'' and inserting ''505B, 510(k), 515, and 520(m)'';

(ii) by striking subparagraph (B) and inserting the following:

''(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;''; and

(iii) in subparagraph (C), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

SEC. 307. POSTMARKET SURVEILLANCE.

Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by amending the section heading and designation to read as follows:

''SEC. 522. POSTMARKET SURVEILLANCE.'';

(2) by striking subsection (a) and inserting the following:

''(a) POSTMARKET SURVEILLANCE.—

''(1) IN GENERAL.—

''(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

''(i) the failure of which would be reasonably likely to have serious adverse health consequences;

''(ii) that is expected to have significant use in pediatric populations; or

''(iii) that is intended to be—

''(I) implanted in the human body for more than 1 year; or

''(II) a life-sustaining or life-supporting device used outside a device user facility.

''(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

''(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.''; and

(3) in subsection (b)—

(A) by striking ''(b) SURVEILLANCE APPROVAL.—Each'' and inserting the following:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each'';

(B) by striking ''The Secretary, in consultation'' and inserting ''Except as provided in paragraph (2), the Secretary, in consultation'';

(C) by striking ''Any determination'' and inserting ''Except as provided in paragraph (2), any determination''; and

(D) by adding at the end the following:

''(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

''(c) DISPUTE RESOLUTION.—A manufacturer may request review under section 562 of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 301(q)(1)(C), adulterated under section 501(f)(1), misbranded under section 502(t)(3), or in violation of, as applicable, section 510(k) or section 515, unless deemed necessary to protect the public health.''.

TITLE IV—PEDIATRIC RESEARCH EQUITY ACT OF 2007

SEC. 401. SHORT TITLE.

This title may be cited as the ''Pediatric Research Equity Act of 2007''.

SEC. 402. REAUTHORIZATION OF PEDIATRIC RESEARCH EQUITY ACT.

(a) IN GENERAL.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended to read as follows:

''SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

''(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—A person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application)—

''(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

''(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

''(2) ASSESSMENTS.—

''(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

''(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

''(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

''(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

''(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

''(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

''(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

''(3) DEFERRAL.—

''(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(i) the Secretary finds that—

''(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

''(III) there is another appropriate reason for deferral; and

''(ii) the applicant submits to the Secretary—

''(I) certification of the grounds for deferring the assessments;

''(II) a description of the planned or ongoing studies;

''(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

''(IV) a timeline for the completion of such studies.

''(B) ANNUAL REVIEW.—

''(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

''(I) Information detailing the progress made in conducting pediatric studies.

''(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

''(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.

''(4) WAIVERS.—

''(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

''(II) is not likely to be used in a substantial number of pediatric patients.

''(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

''(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

''(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

''(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

''(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—After providing notice in the form of a letter (that, for a drug approved under section 505, references a declined written request under section 505A for a labeled indication which written request is not referred under section 505A(n)(1)(A) to the Foundation of the National Institutes of Health for the pediatric studies), the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

''(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

''(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

''(2) WAIVERS.—

''(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

''(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial

waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii)(I) the drug or biological product—

''(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

''(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

''(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

''(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

''(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

''(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

''(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

''(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

''(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit an assessment described in subsection (a)(2), or a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b)—

''(1) the drug or biological product that is the subject of the assessment or request may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303); but

''(2) the failure to submit the assessment or request shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

''(e) MEETINGS.—Before and during the investigational process for a new drug or biological product, the Secretary shall meet at appropriate times with the sponsor of the new drug or biological product to discuss—

''(1) information that the sponsor submits on plans and timelines for pediatric studies; or

''(2) any planned request by the sponsor for waiver or deferral of pediatric studies.

''(f) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—

''(1) REVIEW.—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on all pediatric plans and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral and waiver requests granted pursuant to this section.

''(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in such activity.

''(4) REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.—Consultation on pediatric plans and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

''(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

''(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

''(A) the number of assessments conducted under this section;

''(B) the specific drugs and biological products and their uses assessed under this section;

''(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the total number of deferrals requested and granted under this section and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

''(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

''(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

''(G) the labeling changes made as a result of assessments conducted under this section;

''(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

''(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and

''(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.

''(g) LABELING CHANGES.—

''(1) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude,

delay, or serve as the basis to stay the other course of action.

''(2) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the label of such product to include information about the results of the assessment and a statement of the Secretary's determination.

''(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 210 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration.

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

''(i) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the one-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

''(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

''(k) ORPHAN DRUGS.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526.

''(l) INSTITUTE OF MEDICINE STUDY.—

''(1) IN GENERAL.—Not later than three years after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to this section or precursor regulations since 1997 and labeling changes made as a result of such studies.

''(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, the number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

''(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to this section from each review division within the Center for Drug Evaluation and Research in order to make the requested assessment.

''(m) INTEGRATION WITH OTHER PEDIATRIC STUDIES.—The authority under this section shall remain in effect so long as an application subject to this section may be accepted for filing by the Secretary on or before the date specified in section 505A(q).''.

(b) APPLICABILITY.—

(1) IN GENERAL.—Notwithstanding subsection (h) of section 505B of the Federal Food, Drug and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, a pending assessment, including a deferred assessment, required under such section 505B shall be deemed to have been required under section 505B of the Federal Food, Drug and Cosmetic Act as in effect on or after the date of the enactment of this Act.

(2) CERTAIN ASSESSMENTS AND WAIVER REQUESTS.—An assessment pending on or after the date that is 1 year prior to the date of the enactment of this Act shall be subject to the tracking and disclosure requirements established under such section 505B, as in effect on or after such date of enactment, except that any such assessments submitted or waivers of such assessments requested before such date of enactment shall not be subject to subsections (a)(4)(C), (b)(2)(C), (f)(6)(F), and (h) of such section 505B.

SEC. 403. ESTABLISHMENT OF INTERNAL COMMITTEE.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, AND WAIVERS.

''The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 505A(f) and 505B(f). Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.''.

SEC. 404. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.

Not later than January 1, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to the Congress a report that addresses the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested and properly labeled. Such report shall include—

(1) the number and importance of drugs and biological products for children that are being tested as a result of the amendments made by this title and title V and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs and biological products for children that are not being tested for their use notwithstanding the provisions of this title and title V and possible reasons for the lack of testing;

(3) the number of drugs and biological products for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this title, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

TITLE V—BEST PHARMACEUTICALS FOR CHILDREN ACT OF 2007

SEC. 501. SHORT TITLE.

This title may be cited as the ''Best Pharmaceuticals for Children Act of 2007''.

SEC. 502. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT.

(a) PEDIATRIC STUDIES OF DRUGS.—

(1) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended to read as follows:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

''(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

''(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(E) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

''(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

''(B)(i) if the drug is the subject of—

''(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(II) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3)—

''(A)(i)(I) the period referred to in subsection (c)(3)(E)(ii) of section 505, and in subsection (j)(5)(F)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(II) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(5)(F) of such section, is deemed to be three years and six months rather than three years; and

''(ii) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

''(B)(i) if the drug is the subject of—

''(I) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(II) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B)(ii) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(ii) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(5)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions)

''(2) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (1)(A) or (1)(B) if the determination made under subsection (d)(3) is made later than 9 months prior to the expiration of such period.

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

''(B) SINGLE WRITTEN REQUEST.—A single written request—

''(i) may relate to more than one use of a drug; and

''(ii) may include uses that are both approved and unapproved.

''(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

''(A) REQUEST AND RESPONSE.—

''(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

''(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

''(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.

''(ii) DISAGREE WITH REQUEST.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

''(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as the submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

''(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

''(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

''(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within one year after the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such one year period.

''(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

''(1) INTERNAL REVIEW.—The Secretary shall utilize the internal review committee established under section 505C to review all written requests issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with paragraph (2).

''(2) REVIEW OF WRITTEN REQUESTS.—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.

''(3) REVIEW OF PEDIATRIC STUDIES.—The committee referred to in paragraph (1) may review studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject such reports under subsection (d)(3).

''(4) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

''(5) DOCUMENTATION OF COMMITTEE ACTION.—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in such activity.

''(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

''(A) the number of studies conducted under this section and under section 409I of the Public Health Service Act;

''(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under such sections;

''(C) the types of studies conducted under such sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

''(E) the labeling changes made as a result of studies conducted under such sections;

''(F) an annual summary of labeling changes made as a result of studies conducted under such sections for distribution pursuant to subsection (k)(2); and

''(G) information regarding reports submitted on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.

''(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the six-month period under subsection (b) or (c) has already been applied—

''(1) may receive an additional six-month period under subsection (c)(1)(A)(i)(II) for a supplemental application if all other requirements under this section are satisfied, except that such drug may not receive any additional such period under subsection (c)(1)(B); and

''(2) may not receive any additional such period under subsection (c)(1)(A)(ii).

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Notwithstanding any other provision of law, if any pediatric study is required by a provision of law (including a regulation) other than this section and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

''(i) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS.—Any application or supplement to an application under section 505 proposing a labeling change as a result of any pediatric study conducted pursuant to this section—

''(A) shall be considered to be a priority application or supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(j) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.

''(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall include as a requirement of a written request that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(3)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, during the one-year period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the reports, the Director of such Office shall provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this Act in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the one-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

''(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

''(2) the date on which the 6-month exclusivity period expires, by the number of days of the overlap if the 180-day period would, but for the application of this subsection, expire during the six-month exclusivity period.

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under section 505C, determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

''(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B(b). Prior to making such a determination, the Secretary may not take more than 30 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate and fund all of the studies in the written request in their entirety within the timeframes specified within the written request. Only if the Secretary makes such certification in the affirmative, the Secretary

shall refer all pediatric studies in the written request to the Foundation for the National Institutes of Health for the conduct of such studies, and such Foundation shall fund such studies. If no certification has been made at the end of the 30-day period, or if the Secretary certifies that funds are not sufficient to initiate and fund all the studies in their entirety, the Secretary shall consider whether assessments shall be required under section 505B(b) for such drug.

''(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

''(2) PUBLIC NOTICE.—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

''(o) PROMPT APPROVAL OF DRUGS UNDER SECTION 505(j) WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

''(1) GENERAL RULE.—A drug for which an application has been submitted or approved under section 505(j) shall not be considered ineligible for approval under that section or misbranded under section 502 on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F).

''(2) LABELING.—Notwithstanding clauses (iii) and (iv) of section 505(j)(5)(F), the Secretary may require that the labeling of a drug approved under section 505(j) that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

''(A) a statement that, because of marketing exclusivity for a manufacturer—

''(i) the drug is not labeled for pediatric use; or

''(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

''(B) a statement of any appropriate pediatric contraindications, warnings, or precautions that the Secretary considers necessary.

''(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND OTHER PROVISIONS.—This subsection does not affect—

''(A) the availability or scope of exclusivity under this section;

''(B) the availability or scope of exclusivity under section 505 for pediatric formulations;

''(C) the question of the eligibility for approval of any application under section 505(j) that omits any other conditions of approval entitled to exclusivity under clause (iii) or (iv) of section 505(j)(5)(F); or

''(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505.

''(p) INSTITUTE OF MEDICINE STUDY.—Not later than 3 years after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to this section. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to this section in order to conduct such study. Such study shall—

''(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c);

''(2) review and assess such representative pediatric studies conducted under subsections (b) and (c) since 1997 and labeling changes made as a result of such studies;

''(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials;

''(4) review and assess the pediatric studies of biological products as required under subsections (a) and (b) of section 505B; and

''(5) make recommendations regarding appropriate incentives for encouraging pediatric studies of biologics.

''(q) SUNSET.—A drug may not receive any 6-month period under subsection (b) or (c) unless—

''(1) on or before October 1, 2012, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2012, an application for the drug is accepted for filing under section 505(b); and

''(3) all requirements of this section are met.''.

(2) APPLICABILITY.—

(A) IN GENERAL.—The amendment made by this subsection shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) issued on or after the date of the enactment of this Act.

(B) CERTAIN WRITTEN REQUESTS.—A written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, which has been accepted and for which no determination under subsection (d)(2) of such section has been made before such date of enactment, shall be subject to such section 505A, except that such written requests shall be subject to subsections (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j), (k)(1), (l)(1), and (n) of section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on or after the date of the enactment of this Act.

(b) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended to read as follows:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every three years.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

''(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

''(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

''(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) there is a submitted application that could be approved under the criteria of such section; and

''(B) there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and

''(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

''(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of such Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

''(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

''(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

''(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(6) REPORTING OF STUDIES.—

''(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

''(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

''(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

''(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

''(8) DISPUTE RESOLUTION.—

''(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

''(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

''(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

''(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

''(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

''(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

''(B) such sums as are necessary for each of the four succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

(c) FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of this Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)'' and inserting ''and studies for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

(d) CONTINUATION OF OPERATION OF COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following new subsection:

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.''.

(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.—Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking ''and'' after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subparagraph:

''(D) provide recommendations to the internal review committee created under section 505B(f) of the Federal Food, Drug, and Cosmetic Act regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following new paragraph:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act, the Subcommittee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

(f) EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.—

(1) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the ''Administrative Procedure Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products,'' 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(2) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(A) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(C) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

SEC. 503. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: '', including pediatric pharmacological research''.

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting ''including pediatric pharmacological research,'' after ''pediatric research,''.

TITLE VI—REAGAN-UDALL FOUNDATION

SEC. 601. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

''SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

''(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the 'Foundation') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

''(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

''(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

''(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify

unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

''(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

''(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

''(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

''(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

''(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

''(7) ensure that—

''(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

''(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

''(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

''(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

''(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

''(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

''(d) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Commissioner.

''(ii) The Director of the National Institutes of Health.

''(iii) The Director of the Centers for Disease Control and Prevention.

''(iv) The Director of the Agency for Healthcare Research and Quality.

''(C) APPOINTED MEMBERS.—

''(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of such appointed members—

''(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

''(II) 3 shall be representatives of academic research organizations;

''(III) 2 shall be representatives of patient or consumer advocacy organizations;

''(IV) 1 shall be a representative of health care providers; and

''(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

''(ii) REQUIREMENTS.—

''(I) EXPERTISE.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

''(II) FEDERAL EMPLOYEES.—No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B).

''(D) INITIAL MEETING.—

''(i) IN GENERAL.—Not later than 30 days after the date of the enactment of this subchapter, the Secretary shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II)—

''(I) the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate; and

''(II) the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.

''(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

''(2) DUTIES OF BOARD.—The Board shall—

''(A) establish bylaws for the Foundation that—

''(i) are published in the Federal Register and available for public comment;

''(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

''(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

''(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

''(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

''(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

''(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

''(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

''(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

''(x) specify a process for annual Board review of the operations of the Foundation; and

''(xi) establish specific duties of the Executive Director;

''(B) prioritize and provide overall direction to the activities of the Foundation;

''(C) evaluate the performance of the Executive Director; and

''(D) carry out any other necessary activities regarding the functioning of the Foundation.

''(3) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (g), as may be necessary to ensure that the Foundation maintains status as an organization that—

''(1) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

''(2) is, under subsection (a) of such section, exempt from taxation.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

''(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

''(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

''(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

''(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

''(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

''(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

''(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

''(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

''(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

''(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

''(l) ANNUAL REPORTS.—

''(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

''(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

''(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

''(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

''(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

''(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury are held in separate accounts from funds received from entities under subsection (i).

''(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).''.

(b) OTHER FOUNDATION PROVISIONS.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by subsection (a)) is amended by adding at the end the following:

''SEC. 771. LOCATION OF FOUNDATION.

''The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

''SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.

''(a) IN GENERAL.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 770(l)(2).

''(b) REPORT TO CONGRESS.—Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 770(l)(2) and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the Food and Drug Administration.

''(c) EXTRAMURAL GRANTS.—The provisions of this subchapter and section 566 shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after the date of the enactment of this subchapter.''.

(c) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) is amended by adding at the end the following: ''Any such fellowships and training programs under this section or under section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.''.

SEC. 602. OFFICE OF THE CHIEF SCIENTIST.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 910. OFFICE OF THE CHIEF SCIENTIST.

''(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

''(b) DUTIES OF THE OFFICE.—The Office of the Chief Scientist shall—

''(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

''(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

''(3) develop and advocate for a budget to support intramural research;

''(4) develop a peer review process by which intramural research can be evaluated;

''(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

''(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

''(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health; and

''(6) develop postmarket safety performance measures that are as measurable and rigorous as the ones already developed for premarket review.''.

SEC. 603. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

''(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-

Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

''(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means an entity that meets each of the following:

''(1) The entity is—

''(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965) or a consortium of such institutions; or

''(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

''(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

''(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

''(A) developing and critically evaluating tools, methods, and processes—

''(i) to increase efficiency, predictability, and productivity of medical product development; and

''(ii) to more accurately identify the benefits and risks of new and existing medical products;

''(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

''(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

''(c) FUNDING.—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

''(d) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

''(1) reviewing the operations and activities of the Partnerships in the previous year; and

''(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

''(e) DEFINITION.—In this section, the term 'medical product' includes a drug, a biological product as defined in section 351 of the Public Health Service Act, a device, and any combination of such products.

''(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.''.

TITLE VII—CONFLICTS OF INTEREST

SEC. 701. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

''SEC. 712. CONFLICTS OF INTEREST.

''(a) DEFINITIONS.—For purposes of this section:

''(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

''(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

''(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

''(1) RECRUITMENT.—

''(A) IN GENERAL.—The Secretary shall—

''(i) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups;

''(ii) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities; and

''(iii) take into account the advisory committees with the greatest number of vacancies.

''(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

''(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

''(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(2) of this section for service on the committee at a meeting of the committee.

''(c) DISCLOSURES; PROHIBITIONS ON PARTICIPATION; WAIVERS.—

''(1) DISCLOSURE OF FINANCIAL INTEREST.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

''(2) PROHIBITIONS AND WAIVERS ON PARTICIPATION.—

''(A) IN GENERAL.—Except as provided under subparagraph (B), a member of an advisory committee may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

''(B) WAIVER.—If the Secretary determines it necessary to afford the advisory committee essential expertise, the Secretary may grant a waiver of the prohibition in subparagraph (A) to permit a member described in such subparagraph to—

''(i) participate as a non-voting member with respect to a particular matter considered in a committee meeting; or

''(ii) participate as a voting member with respect to a particular matter considered in a committee meeting.

''(C) LIMITATION ON WAIVERS AND OTHER EXCEPTIONS.—

''(i) DEFINITION.—For purposes of this subparagraph, the term 'exception' means each of the following with respect to members of advisory committees:

''(I) A waiver under section 505(n)(4) (as in effect on the day before the date of the enactment of the Food and Drug Administration Amendments Act of 2007).

''(II) A written determination under section 208(b) of title 18, United States Code.

''(III) A written certification under section 208(b)(3) of such title.

''(ii) DETERMINATION OF TOTAL NUMBER OF MEMBERS SLOTS AND MEMBER EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine—

''(I)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who participated in the meeting; and

''(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the ''total number of 2007 meeting slots''); and

''(II)(aa) for each meeting held by any advisory committee during fiscal year 2007, the number of members who received an exception for the meeting; and

''(bb) the sum of the respective numbers determined under item (aa) (referred to in this subparagraph as the ''total number of 2007 meeting exceptions'').

''(iii) DETERMINATION OF PERCENTAGE REGARDING EXCEPTIONS DURING FISCAL YEAR 2007.—The Secretary shall determine the percentage constituted by—

''(I) the total number of 2007 meeting exceptions; divided by

''(II) the total number of 2007 meeting slots.

''(iv) LIMITATION FOR FISCAL YEARS 2008 THROUGH 2012.—The number of exceptions at the Food and Drug Administration for members of advisory committees for a fiscal year may not exceed the following:

''(I) For fiscal year 2008, 95 percent of the percentage determined under clause (iii) (referred to in this clause as the ''base percentage'').

''(II) For fiscal year 2009, 90 percent of the base percentage.

''(III) For fiscal year 2010, 85 percent of the base percentage.

''(IV) For fiscal year 2011, 80 percent of the base percentage.

''(V) For fiscal year 2012, 75 percent of the base percentage.

''(v) ALLOCATION OF EXCEPTIONS.—The exceptions authorized under clause (iv) for a fiscal year may be allocated within the centers or other organizational units of the Food and Drug Administration as determined appropriate by the Secretary.

''(3) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

''(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in subparagraph (B)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet Web site of the Food and Drug Administration—

''(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

''(ii) the reasons of the Secretary for such determination, certification, or waiver.

''(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (2)(B) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet Web site of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

''(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(3) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

''(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

''(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(3) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

''(3) with respect to such year, the number of times the disclosures required under subsection (c)(3) occurred under subparagraph (B) of such subsection; and

''(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

''(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.''.

(b) CONFORMING AMENDMENTS.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

TITLE VIII—CLINICAL TRIAL DATABASES

SEC. 801. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by—

(1) redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the following:

''(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

''(1) DEFINITIONS; REQUIREMENT.—

''(A) DEFINITIONS.—In this subsection:

''(i) APPLICABLE CLINICAL TRIAL.—The term 'applicable clinical trial' means an applicable device clinical trial or an applicable drug clinical trial.

''(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The term 'applicable device clinical trial' means—

''(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

''(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

''(iii) APPLICABLE DRUG CLINICAL TRIAL.—

''(I) IN GENERAL.—The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

''(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term 'clinical investigation' has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

''(III) PHASE I.—For purposes of subclause (I), the term 'phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

''(iv) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

''(v) COMPLETION DATE.—The term 'completion date' means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

''(vi) DEVICE.—The term 'device' means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

''(vii) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

''(viii) ONGOING.—The term 'ongoing' means, with respect to a clinical trial of a drug or a device and to a date, that—

''(I) 1 or more patients is enrolled in the clinical trial; and

''(II) the date is before the completion date of the clinical trial.

''(ix) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug or device, means—

''(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

''(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

''(B) REQUIREMENT.—The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

''(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—

''(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

''(ii) CONTENT.—The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

''(I) descriptive information, including—

''(aa) a brief title, intended for the lay public;

''(bb) a brief summary, intended for the lay public;

''(cc) the primary purpose;

''(dd) the study design;

''(ee) for an applicable drug clinical trial, the study phase;

''(ff) study type;

''(gg) the primary disease or condition being studied, or the focus of the study;

''(hh) the intervention name and intervention type;

''(ii) the study start date;

''(jj) the expected completion date;

''(kk) the target number of subjects; and

''(ll) outcomes, including primary and secondary outcome measures;

''(II) recruitment information, including—

''(aa) eligibility criteria;

''(bb) gender;

''(cc) age limits;

''(dd) whether the trial accepts healthy volunteers;

''(ee) overall recruitment status;

''(ff) individual site status; and

''(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

''(III) location and contact information, including—

''(aa) the name of the sponsor;

''(bb) the responsible party, by official title; and

''(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

''(IV) administrative data (which the Secretary may make publicly available as necessary), including—

''(aa) the unique protocol identification number;

''(bb) other protocol identification numbers, if any; and

''(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

''(iii) MODIFICATIONS.—The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

''(B) FORMAT AND STRUCTURE.—

''(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:

''(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(II) The name of the intervention, including any drug or device being studied in the clinical trial.

''(III) The location of the clinical trial.

''(IV) The age group studied in the clinical trial, including pediatric subpopulations.

''(V) The study phase of the clinical trial.

''(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.

''(VII) The recruitment status of the clinical trial.

''(VIII) The National Clinical Trial number or other study identification for the clinical trial.

''(ii) ADDITIONAL SEARCHABLE CATEGORY.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

''(iii) OTHER ELEMENTS.—The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

''(iv) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

''(C) DATA SUBMISSION.—The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of—

''(i) 90 days after such date of enactment;

''(ii) 21 days after the first patient is enrolled in such clinical trial; or

''(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment.

''(D) POSTING OF DATA.—

''(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

''(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

''(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date; or

''(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

''(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

''(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

''(i) IN GENERAL.—Beginning not later than 90 days after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

''(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

''(ii) REQUIRED INFORMATION.—

''(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

''(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

''(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

''(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.

''(ee) For an applicable device clinical trial, in the case of a premarket application under section 515 of the Federal Food, Drug, and Cosmetic Act, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of such Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

''(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

''(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

''(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Food and Drug Administration Amendments Act of 2007, as available.

''(B) INCLUSION OF RESULTS.—The Secretary, acting through the Director of NIH, shall—

''(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the 'registry and results data bank');

''(ii) ensure that such results are made publicly available through the Internet;

''(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

''(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

''(C) BASIC RESULTS.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall include in the registry and results data bank the following elements for drugs that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act and devices that are cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act:

''(i) DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE.—A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

''(ii) PRIMARY AND SECONDARY OUTCOMES.—The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

''(iii) POINT OF CONTACT.—A point of contact for scientific information about the clinical trial results.

''(iv) CERTAIN AGREEMENTS.—Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

''(D) EXPANDED REGISTRY AND RESULTS DATA BANK.—

''(i) EXPANSION BY RULEMAKING.—To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

''(ii) CLINICAL TRIALS.—

''(I) APPROVED PRODUCTS.—The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

''(aa) each applicable drug clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act; and

''(bb) each applicable device clinical trial for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.

''(II) UNAPPROVED PRODUCTS.—The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

''(aa) an applicable drug clinical trial for a drug that is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act and not licensed under section 351 of this Act (whether approval or licensure was sought or not); and

''(bb) an applicable device clinical trial for a device that is not cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act (whether clearance or approval was sought or not).

''(iii) REQUIRED ELEMENTS.—The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

''(I) A summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

''(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

''(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

''(IV) Such other categories as the Secretary determines appropriate.

''(iv) RESULTS SUBMISSION.—The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

''(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

''(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

''(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

''(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

''(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

''(v) ADDITIONAL PROVISIONS.—The regulations under this subparagraph shall also establish—

''(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

''(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

''(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

''(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

''(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

''(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

''(vi) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

''(vii) PUBLIC MEETING.—The Secretary shall hold a public meeting no later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

''(E) SUBMISSION OF RESULTS INFORMATION.—

''(i) IN GENERAL.—Except as provided in clause (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

''(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); or

''(II) the actual date of completion.

''(ii) CLINICAL TRIALS DESCRIBED.—An applicable clinical trial described in this clause is an applicable clinical trial subject to—

''(I) paragraph (2)(C); and

''(II)(aa) subparagraph (C); or

''(bb) the regulations issued under subparagraph (D).

''(iii) DELAYED SUBMISSION OF RESULTS WITH CERTIFICATION.—If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

''(iv) SEEKING INITIAL APPROVAL OF A DRUG OR DEVICE.—With respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, and Cosmetic Act or initially licensed under section 351 of this Act, or the device is initially cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m), as applicable.

''(v) SEEKING APPROVAL OF A NEW USE FOR THE DRUG OR DEVICE.—

''(I) IN GENERAL.—With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act, licensing under section 351 of this Act, or clearance under section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

''(aa) the new use of the drug or device is approved under such section 505, licensed under such section 351, cleared under such section 510(k), or approved under such section 515 or 520(m);

''(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 505, 351, 510(k), 515, or 520(m); or

''(cc) except as provided in subclause (III), the application or premarket notification under such section 505, 351, 510(k), 515, or 520(m) is withdrawn without resubmission for no less than 210 days.

''(II) REQUIREMENT THAT EACH CLINICAL TRIAL IN APPLICATION BE TREATED THE SAME.—If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable) of the use studied in the clinical trial.

''(III) TWO-YEAR LIMITATION.—The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

''(vi) EXTENSIONS.—The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

''(F) NOTICE TO DIRECTOR OF NIH.—The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

''(G) POSTING OF DATA.—The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

''(H) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

''(I) ADVERSE EVENTS.—

''(i) REGULATIONS.—Not later than 18 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for drugs described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

''(ii) DEFAULT.—If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, clause (iii) shall take effect.

''(iii) ADDITIONAL ELEMENTS.—Upon the application of clause (ii), the Secretary shall include in the registry and results data bank for drugs described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

''(I) SERIOUS ADVERSE EVENTS.—A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

''(II) FREQUENT ADVERSE EVENTS.—A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

''(iv) POSTING OF OTHER INFORMATION.—In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

''(v) RELATION TO SUBPARAGRAPH (C).—Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

''(4) ADDITIONAL SUBMISSIONS OF CLINICAL TRIAL INFORMATION.—

''(A) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 351 or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

''(B) REQUIRED SUBMISSIONS.—

''(i) IN GENERAL.—Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

''(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

''(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

''(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

''(ii) CLINICAL TRIALS DESCRIBED.—A clinical trial described in this clause is—

''(I) an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

''(II) an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)).

''(C) UPDATES TO CLINICAL TRIAL DATA BANK.—

''(i) SUBMISSION OF UPDATES.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

''(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

''(II) shall include identification of the dates of any such changes;

''(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

''(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

''(ii) PUBLIC AVAILABILITY OF UPDATES.—The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

''(5) COORDINATION AND COMPLIANCE.—

''(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

''(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2) and (3).

''(ii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

''(iii) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such noncompliance and submit the required clinical trial information.

''(iv) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

''(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

''(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraph (2) and (3).

''(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met.

Where available, such certification shall include the appropriate National Clinical Trial control numbers.

''(C) QUALITY CONTROL.—

''(i) PILOT QUALITY CONTROL PROJECT.—Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

''(ii) NOTICE OF COMPLIANCE.—If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

''(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of—

''(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

''(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

''(E) PUBLIC NOTICES.—

''(i) NOTICE OF VIOLATIONS.—If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

''(I) that the responsible party is not in compliance with this Act by—

''(aa) failing to submit required clinical trial information; or

''(bb) submitting false or misleading clinical trial information;

''(II) of the penalties imposed for the violation, if any; and

''(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

''(ii) NOTICE OF FAILURE TO SUBMIT PRIMARY AND SECONDARY OUTCOMES.—If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this act, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

''(iii) FAILURE TO SUBMIT STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: 'The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.'.

''(iv) SUBMISSION OF FALSE INFORMATION STATEMENT.—The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: 'The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.'.

''(v) NON-SUBMISSION OF STATEMENT.—The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: 'The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.'

''(vi) COMPLIANCE SEARCHES.—The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

''(6) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

''(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

''(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

''(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

''(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

''(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

''(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).''.

(2) CIVIL MONEY PENALTIES.—Subsection (f) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as redesignated by section 226, is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (5), (6), and (7), respectively;

(B) by inserting after paragraph (2) the following:

''(3)(A) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

''(B) If a violation of section 301(jj) is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii), the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.'';

(C) in paragraph (2)(C), by striking ''paragraph (3)(A)'' and inserting ''paragraph (5)(A)'';

(D) in paragraph (5), as so redesignated, by striking ''paragraph (1) or (2)'' each place it appears and inserting ''paragraph (1), (2),or (3)'';

(E) in paragraph (6), as so redesignated, by striking ''paragraph (3)(A)'' and inserting ''paragraph (5)(A)''; and

(F) in paragraph (7), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (6)''.

(3) NEW DRUGS AND DEVICES.—

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: ''The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.''.

(B) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.''.

(C) DEVICE REPORTS UNDER SECTION 510(k).—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

''A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.''.

(D) DEVICE PREMARKET APPROVAL APPLICATION.—Section 515(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(1)) is amended—

(i) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

''(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and''.

(E) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ''and such application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application)''.

(c) SURVEILLANCES.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidance on how the requirements of section 402(j) of the Public Health Service Act, as added by this section, apply to a pediatric postmarket surveillance described in paragraph (1)(A)(ii)(II) of such section 402(j) that is not a clinical trial.

(d) PREEMPTION.—

(1) IN GENERAL.—Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act, as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if

submitted in compliance with subsection (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the registry and results data bank under such subsection (j), if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE IX—ENHANCED AUTHORITIES REGARDING POSTMARKET SAFETY OF DRUGS

Subtitle A—Postmarket Studies and Surveillance

SEC. 901. POSTMARKET STUDIES AND CLINICAL TRIALS REGARDING HUMAN DRUGS; RISK EVALUATION AND MITIGATION STRATEGIES.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following subsections:

''(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

''(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

''(2) DEFINITIONS.—For purposes of this subsection:

''(A) RESPONSIBLE PERSON.—The term 'responsible person' means a person who—

''(i) has submitted to the Secretary a covered application that is pending; or

''(ii) is the holder of an approved covered application.

''(B) COVERED APPLICATION.—The term 'covered application' means—

''(i) an application under subsection (b) for a drug that is subject to section 503(b); and

''(ii) an application under section 351 of the Public Health Service Act.

''(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms 'new safety information', 'serious risk', and 'signal of a serious risk' have the meanings given such terms in section 505–1(b).

''(3) STUDIES AND CLINICAL TRIALS.—

''(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

''(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

''(i) To assess a known serious risk related to the use of the drug involved.

''(ii) To assess signals of serious risk related to the use of the drug.

''(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

''(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

''(D) DETERMINATION BY SECRETARY.—

''(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

''(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

''(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

''(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

''(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

''(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

''(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

''(A) NEW SAFETY INFORMATION.—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

''(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

''(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or

''(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

''(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

''(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

''(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

''(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

''(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

''(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

''(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

''(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a

drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

''(p) RISK EVALUATION AND MITIGATION STRATEGY.—

''(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

''(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

''(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

''(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

''(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).''.

(b) REQUIREMENTS REGARDING STRATEGIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following section:

''SEC. 505–1. RISK EVALUATION AND MITIGATION STRATEGIES.

''(a) SUBMISSION OF PROPOSED STRATEGY.—

''(1) INITIAL APPROVAL.—If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

''(A) The estimated size of the population likely to use the drug involved.

''(B) The seriousness of the disease or condition that is to be treated with the drug.

''(C) The expected benefit of the drug with respect to such disease or condition.

''(D) The expected or actual duration of treatment with the drug.

''(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

''(F) Whether the drug is a new molecular entity.

''(2) POSTAPPROVAL REQUIREMENT.—

''(A) IN GENERAL.—If the Secretary has approved a covered application (including an application approved before the effective date of this section) and did not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the offices described in paragraph (1), may subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

''(B) SUBMISSION OF PROPOSED STRATEGY.—Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

''(3) ABBREVIATED NEW DRUG APPLICATIONS.—The applicability of this section to an application under section 505(j) is subject to subsection (i).

''(4) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

''(b) DEFINITIONS.—For purposes of this section:

''(1) ADVERSE DRUG EXPERIENCE.—The term 'adverse drug experience' means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

''(A) an adverse event occurring in the course of the use of the drug in professional practice;

''(B) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

''(C) an adverse event occurring from abuse of the drug;

''(D) an adverse event occurring from withdrawal of the drug; and

''(E) any failure of expected pharmacological action of the drug.

''(2) COVERED APPLICATION.—The term 'covered application' means an application referred to in section 505(p)(1)(A).

''(3) NEW SAFETY INFORMATION.—The term 'new safety information', with respect to a drug, means information derived from a clinical trial, an adverse event report, a postapproval study (including a study under section 505(o)(3)), or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system under section 505(k); or other scientific data deemed appropriate by the Secretary about—

''(A) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing information) since the drug was approved, since the risk evaluation and mitigation strategy was required, or since the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

''(B) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

''(4) SERIOUS ADVERSE DRUG EXPERIENCE.—The term 'serious adverse drug experience' is an adverse drug experience that—

''(A) results in—

''(i) death;

''(ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

''(iii) inpatient hospitalization or prolongation of existing hospitalization;

''(iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

''(v) a congenital anomaly or birth defect; or

''(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

''(5) SERIOUS RISK.—The term 'serious risk' means a risk of a serious adverse drug experience.

''(6) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience associated with use of a drug and derived from—

''(A) a clinical trial;

''(B) adverse event reports;

''(C) a postapproval study, including a study under section 505(o)(3);

''(D) peer-reviewed biomedical literature;

''(E) data derived from the postmarket risk identification and analysis system under section 505(k)(4); or

''(F) other scientific data deemed appropriate by the Secretary.

''(7) RESPONSIBLE PERSON.—The term 'responsible person' means the person submitting a covered application or the holder of the approved such application.

''(8) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

''(c) CONTENTS.—A proposed risk evaluation and mitigation strategy under subsection (a) shall—

''(1) include the timetable required under subsection (d); and

''(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

''(d) MINIMAL STRATEGY.—For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that—

''(1) includes an assessment, by the date that is 18 months after the strategy is initially approved;

''(2) includes an assessment by the date that is 3 years after the strategy is initially approved;

''(3) includes an assessment in the seventh year after the strategy is so approved; and

''(4) subject to paragraphs (1), (2), and (3)—

''(A) is at a frequency specified in the strategy;

''(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

''(C) is eliminated after the 3-year period described in paragraph (1) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

''(e) ADDITIONAL POTENTIAL ELEMENTS OF STRATEGY.—

''(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), may under such subsection require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

''(2) MEDICATION GUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

''(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

''(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

''(3) COMMUNICATION PLAN.—The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy (including under this paragraph). Such plan may include—

''(A) sending letters to health care providers;

''(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests); or

''(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

''(f) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

''(1) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

''(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

''(B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

''(2) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under paragraph (1) shall—

''(A) be commensurate with the specific serious risk listed in the labeling of the drug;

''(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

''(C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

''(i) patients with serious or life-threatening diseases or conditions; and

''(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

''(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

''(i) conform with elements to assure safe use for other drugs with similar, serious risks; and

''(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

''(3) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

''(A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);

''(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

''(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;

''(D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

''(E) each patient using the drug be subject to certain monitoring; or

''(F) each patient using the drug be enrolled in a registry.

''(4) IMPLEMENTATION SYSTEM.—The elements to assure safe use under paragraph (1) that are described in subparagraphs (B), (C), and (D) of paragraph (3) may include a system through which the applicant is able to take reasonable steps to—

''(A) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

''(B) work to improve implementation of such elements by such persons.

''(5) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall—

''(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be—

''(i) unduly burdensome on patient access to the drug; and

''(ii) to the extent practicable, minimize the burden on the health care delivery system;

''(B) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

''(i) assure safe use of the drug;

''(ii) are not unduly burdensome on patient access to the drug; and

''(iii) to the extent practicable, minimize the burden on the health care delivery system; and

''(C) considering such input and evaluations—

''(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

''(ii) modify elements under this subsection for 1 or more drugs as appropriate.

''(6) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this subsection. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.

''(7) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this subsection during the period described in section 319(a) of the Public Health Service Act with respect to a qualified countermeasure described under section 319F–1(a)(2) of such Act, to which a requirement under this subsection has been applied, if the Secretary has—

''(A) declared a public health emergency under such section 319; and

''(B) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

''(8) LIMITATION.—No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 505(b)(2) or (j) or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

''(g) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—

''(1) VOLUNTARY ASSESSMENTS.—After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to paragraph (2), submit to the Secretary an assessment of, and propose a modification to, the approved strategy for the drug involved at any time.

''(2) REQUIRED ASSESSMENTS.—A responsible person shall, subject to paragraph (5), submit an assessment of, and may propose a modification to, the approved risk evaluation and mitigation strategy for a drug—

''(A) when submitting a supplemental application for a new indication for use under section 505(b) or under section 351 of the Public Health Service Act, unless the drug is not subject to section 503(b) and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

''(B) when required by the strategy, as provided for in such timetable under subsection (d);

''(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that new safety or effectiveness information indicates that—

''(i) an element under subsection (d) or (e) should be modified or included in the strategy; or

''(ii) an element under subsection (f) should be modified or included in the strategy; or

''(D) within 15 days when ordered by the Secretary, in consultation with the offices described in subsection (c)(2), if the Secretary determines that there may be a cause for action by the Secretary under section 505(e).

''(3) REQUIREMENTS FOR ASSESSMENTS.—An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include—

''(A) with respect to any goal under subsection (f), an assessment of the extent to which the elements to assure safe use are meeting the goal or whether the goal or such elements should be modified;

''(B) with respect to any postapproval study required under section 505(o) or otherwise undertaken by the responsible person to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered; and

''(C) with respect to any postapproval clinical trial required under section 505(o) or otherwise undertaken by the responsible party to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act.

''(4) MODIFICATION.—A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition

or modification of any element under subsection (d) or the addition, modification, or removal of any element under subsection (e) or (f), such as—

''(A) modifying the timetable for assessments of the strategy as provided in subsection (d)(3), including to eliminate assessments; or

''(B) adding, modifying, or removing an element to assure safe use under subsection (f).

''(h) REVIEW OF PROPOSED STRATEGIES; REVIEW OF ASSESSMENTS OF APPROVED STRATEGIES.—

''(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g).

''(2) DISCUSSION.—The Secretary, in consultation with the offices described in subsection (c)(2), shall initiate discussions with the responsible person for purposes of this subsection to determine a strategy not later than 60 days after any such assessment is submitted or, in the case of an assessment submitted under subsection (g)(2)(D), not later than 30 days after such assessment is submitted.

''(3) ACTION.—

''(A) IN GENERAL.—Unless the dispute resolution process described under paragraph (4) or (5) applies, the Secretary, in consultation with the offices described in subsection (c)(2), shall describe any required risk evaluation and mitigation strategy for a drug, or any modification to any required strategy—

''(i) as part of the action letter on the application, when a proposed strategy is submitted under subsection (a) or a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1); or

''(ii) in an order issued not later than 90 days after the date discussions of such modification begin under paragraph (2), when a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2).

''(B) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under subparagraph (A).

''(C) PUBLIC AVAILABILITY.—Any action letter described in subparagraph (A)(i) or order described in subparagraph (A)(ii) shall be made publicly available.

''(4) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subsection (a)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution procedures as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

''(5) DISPUTE RESOLUTION IN ALL OTHER CASES.—

''(A) REQUEST FOR REVIEW.—

''(i) IN GENERAL.—Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the responsible person may request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation strategy is not subject to review under this paragraph. The preceding sentence does not prohibit review under this paragraph of the particular elements of such a strategy.

''(ii) SCHEDULING.—Upon receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not later than 5 business days of scheduling the dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

''(B) SCHEDULING REVIEW.—If a responsible person requests review under subparagraph (A), the Secretary—

''(i) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

''(ii) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

''(C) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

''(i) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and such a request shall not preclude the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including appeals as described in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level. At the time a review has been scheduled under subparagraph (B) and notice of such review has been posted, the responsible person shall either withdraw the request under subparagraph (A) or terminate the use of such administrative appeals.

''(ii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under subparagraph (G) , the Secretary (in consultation with the offices described in subsection (c)(2)) and the responsible person may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

''(D) MEETING OF THE BOARD.—At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

''(i) hear from both parties via written or oral presentation; and

''(ii) review the dispute.

''(E) RECORD OF PROCEEDINGS.—The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 90 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets and other information that is exempted from disclosure under section 552 of title 5, United States Code, or section 552a of title 5, United States Code.

''(F) RECOMMENDATION OF THE BOARD.—Not later than 5 days after any such meeting, the Drug Safety Oversight Board shall provide a written recommendation on resolving the dispute to the Secretary. Not later than 5 days after the Board provides such written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

''(G) ACTION BY THE SECRETARY.—

''(i) ACTION LETTER.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

''(I) the action deadline for the action letter on the application; or

''(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(ii) ORDER.—With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(H) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under subparagraph (G).

''(I) EFFECT ON ACTION DEADLINE.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline for the action letter on the application if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary—

''(i) has initiated the discussions described under paragraph (2) not less than 60 days before such action deadline; and

''(ii) has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.

''(J) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administrative appeal under subparagraph (C)(i) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for such drug.

''(K) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under subparagraph (D) of the Drug Safety Oversight Board.

''(6) USE OF ADVISORY COMMITTEES.—The Secretary may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

''(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under any of subparagraphs (B) through (D) of subsection (g)(2);

''(B) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

''(C) review a dispute under paragraph (4) or (5).

''(7) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

''(A) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary, in consultation with the offices described in subsection (c)(2), may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened 1 or more public meetings to consider possible responses to such concern.

''(B) NOTICE.—If the Secretary defers an assessment under subparagraph (A), the Secretary shall—

''(i) give notice of the deferral to the holder of the approved covered application not later than 5 days after the deferral;

''(ii) publish the deferral in the Federal Register; and

''(iii) give notice to the public of any public meetings to be convened under subparagraph (A), including a description of the deferral.

''(C) PUBLIC MEETINGS.—Such public meetings may include—

''(i) 1 or more meetings of the responsible person for such drugs;

''(ii) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under paragraph (6); or

''(iii) 1 or more workshops of scientific experts and other stakeholders.

''(D) ACTION.—After considering the discussions from any meetings under subparagraph (A), the Secretary may—

''(i) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

''(ii) seek public comment about such action; and

''(iii) after seeking such comment, issue an order addressing such regulatory action.

''(8) INTERNATIONAL COORDINATION.—The Secretary, in consultation with the offices described in subsection (c)(2), may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under section 505(o)(3), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States. If the Secretary takes action to coordinate such timetable, the Secretary shall give notice to the responsible person.

''(9) EFFECT.—Use of the processes described in paragraphs (7) and (8) shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

''(i) ABBREVIATED NEW DRUG APPLICATIONS.—

''(1) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 505(j) is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) for the applicable listed drug:

''(A) A Medication Guide or patient package insert, if required under subsection (e) for the applicable listed drug.

''(B) Elements to assure safe use, if required under subsection (f) for the listed drug. A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f). The Secretary may waive the requirement under the preceding sentence for a drug that is the subject of an abbreviated new drug application, and permit the applicant to use a different, comparable aspect of the elements to assure safe use, if the Secretary determines that—

''(i) the burden of creating a single, shared system outweighs the benefit of a single, system, taking into consideration the impact on health care providers, patients, the applicant for the abbreviated new drug application, and the holder of the reference drug product; or

''(ii) an aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection, and the applicant for the abbreviated new drug application certifies that it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug and that it was unable to obtain a license.

A certification under clause (ii) shall include a description of the efforts made by the applicant for the abbreviated new drug application to obtain a license. In a case described in clause (ii), the Secretary may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such abbreviated new drug application may use an aspect of the elements to assure safe use, if required under subsection (f) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.

''(2) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under section 505(j), the Secretary—

''(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug; and

''(B) shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

''(j) DRUG SAFETY OVERSIGHT BOARD.—

''(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

''(2) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

''(A) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

''(B) include representatives from offices throughout the Food and Drug Administration, including the offices responsible for postapproval safety of drugs;

''(C) include at least 1 representative each from the National Institutes of Health and the Department of Health and Human Services (other than the Food and Drug Administration);

''(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

''(E) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.''.

(c) REGULATION OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(2), by adding at the end the following:

''(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.''; and

(2) in subsection (j), by inserting '', including the requirements under sections 505(o), 505(p), and 505–1 of such Act,'' after '', and Cosmetic Act''.

(d) ADVERTISEMENTS OF DRUGS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by section 801(b), is amended—

(1) in section 301 (21 U.S.C. 331), by adding at the end the following:

''(kk) The dissemination of a television advertisement without complying with section 503B.''; and

(2) by inserting after section 503A the following:

''SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.

''(a) IN GENERAL.—The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

''(b) REVIEW.—In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

''(1) on changes that are—

''(A) necessary to protect the consumer good and well-being; or

''(B) consistent with prescribing information for the product under review; and

''(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

''(c) NO AUTHORITY TO REQUIRE CHANGES.—Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

''(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY AND ETHNICALLY DIVERSE COMMUNITIES.—In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

''(e) SPECIFIC DISCLOSURES.—

''(1) SERIOUS RISK; SAFETY PROTOCOL.—In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

''(2) DATE OF APPROVAL.—In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 505 or section 351 of the Public Health Service Act, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

''(f) RULE OF CONSTRUCTION.—Nothing in this section may be construed as having any effect on requirements under section 502(n) or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).''.

(3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

(A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: ''In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.''.

(B) REGULATIONS TO DETERMINE CLEAR, CONSPICUOUS, AND NEUTRAL MANNER.—Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by subparagraph (A)) is presented in the manner required under such section.

(4) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 333), as amended by section 801(b), is amended by adding at the end the following:

''(g)(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the person submitted the advertisement for review if required under section 503B.

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

''(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

''(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

''(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the person.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

''(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

''(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

''(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.

(5) REPORT ON DIRECT-TO-CONSUMER ADVERTISING.—Not later than 24 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall utilize the Advisory Committee on Risk Communication established under this Act to advise the Secretary with respect to such report. The Advisory Committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The report required by this paragraph shall recommend effective ways to present and disseminate information to these populations. Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary of Health and Human Services shall submit the report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(6) RULEMAKING.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking ''the procedure specified in section 701(e) of this Act'' and inserting ''section 701(a)''.

(e) RULE OF CONSTRUCTION REGARDING PEDIATRIC STUDIES.—This title and the amendments made by this title may not be construed as affecting the authority of the Secretary of Health and Human Services to request pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act or to require such studies under section 505B of such Act.

SEC. 902. ENFORCEMENT.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible person (as such term is used in section 505–1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

''(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act, as amended by section 801(b), is amended—

(1) by inserting after paragraph (3), as added by section 801(b)(2), the following:

''(4)(A) Any responsible person (as such term is used in section 505–1) that violates a requirement of section 505(o), 505(p), or 505–1 shall be subject to a civil monetary penalty of—

''(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505–1 for which the responsible person is subject to such civil penalty.''; and

(2) in paragraph (5), as redesignated by section 801(b)(2)(A), by striking ''paragraph (1), (2), or (3)'' each place it appears and inserting ''paragraph (1), (2), (3), or (4)''.

SEC. 903. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: ''The

Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).''.

SEC. 904. BENEFIT-RISK ASSESSMENTS.

Not later than 1 year after the date of the enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress a report on how best to communicate to the public the risks and benefits of new drugs and the role of the risk evaluation and mitigation strategy in assessing such risks and benefits. As part of such study, the Commissioner may consider the possibility of including in the labeling and any direct-to-consumer advertisements of a newly approved drug or indication a unique symbol indicating the newly approved status of the drug or indication for a period after approval.

SEC. 905. ACTIVE POSTMARKET RISK IDENTIFICATION AND ANALYSIS.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

''(A) DEFINITION.—In this paragraph, the term 'data' refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

''(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

''(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

''(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

''(I) at least 25,000,000 patients by July 1, 2010; and

''(II) at least 100,000,000 patients by July 1, 2012; and

''(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

''(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

''(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

''(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

''(III) to provide for active adverse event surveillance using the following data sources, as available:

''(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

''(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

''(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

''(IV) to identify certain trends and patterns with respect to data accessed by the system;

''(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

''(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

''(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

''(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

''(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

''(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

''(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

''(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

''(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

''(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

''(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

''(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

''(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

''(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

''(i) priority drug safety questions; and

''(ii) mechanisms for answering such questions, including through—

''(I) active risk identification under paragraph (3); and

''(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

''(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

''(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

''(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

''(II) allow for prompt investigation of priority drug safety questions, including—

''(aa) unresolved safety questions for drugs or classes of drugs; and

''(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

''(III) perform advanced research and analysis on identified drug safety risks;

''(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

''(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

''(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

''(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

''(F) QUALIFIED ENTITIES.—

''(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

''(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

''(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

''(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

''(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

''(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

''(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

''(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

''(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

''(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

''(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

''(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

''(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

''(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

''(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

''(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

''(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

''(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

''(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

''(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

''(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.''.

(b) RULE OF CONSTRUCTION.—Nothing in this section or the amendment made by this section shall be construed to prohibit the lawful disclosure or use of data or information by an entity other than as described in paragraph (4)(B) or (4)(G) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) REPORT TO CONGRESS.—Not later than 4 years after the date of the enactment of this Act, the Secretary shall report to the Congress on the ways in which the Secretary has used the active postmarket risk identification and analysis system described in paragraphs (3) and (4) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), to identify specific drug safety signals and to better understand the outcomes associated with drugs marketed in the United States.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by this section for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out the amendment made by this section, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

(e) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall evaluate data privacy, confidentiality, and security issues relating to accessing, transmitting, and maintaining data for the active postmarket risk identification and analysis system described in paragraphs (3) and (4) of section 505(k) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and make recommendations to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, and any other congressional committees of relevant jurisdiction, regarding the need for any additional legislative or regulatory actions to ensure privacy, confidentiality, and security of this data or otherwise address privacy, confidentiality, and security issues to ensure the effective operation of such active postmarket identification and analysis system.

SEC. 906. STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

(a) PUBLISHED DIRECT-TO-CONSUMER ADVERTISEMENTS.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 901(d)(6), is further amended by inserting ''and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.','' after ''section 701(a),''.

(b) STUDY.—

(1) IN GENERAL.—In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, in consultation with the Advisory Committee on Risk Communication under section 567 of the Federal Food, Drug, and Cosmetic Act (as added by section 917), shall, not later than 6 months after the date of the enactment of this Act, conduct a study to determine if the statement in section 502(n) of such Act (as added by subsection (a)) required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements.

(2) CONTENT.—As part of the study under paragraph (1), such Secretary shall consider whether the information in the statement described in paragraph (1) would detract from the presentation of risk information in a direct-to-consumer television advertisement. If such Secretary determines the inclusion of such statement is appropriate in direct-to-consumer television advertisements, such Secretary shall issue regulations requiring the implementation of such statement in direct-to-consumer television advertisements, including determining a reasonable length of time for displaying the statement in such advertisements. The Secretary shall report to the appropriate committees of Congress the findings of such study and any plans to issue regulations under this paragraph.

SEC. 907. NO EFFECT ON VETERINARY MEDICINE.

This subtitle, and the amendments made by this subtitle, shall have no effect on the use of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 512(a)(5) of such Act.

SEC. 908. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For carrying out this subtitle and the amendments made by this subtitle, there is authorized to be appropriated $25,000,000 for each of fiscal years 2008 through 2012.

(b) RELATION TO OTHER FUNDING.—The authorization of appropriations under subsection (a) is in addition to any other funds available for carrying out this subtitle and the amendments made by this subtitle.

SEC. 909. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATE.—This subtitle takes effect 180 days after the date of the enactment of this Act.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (as added by section 901) (referred to in this section as the ''Act'') if there are in effect on the effective date of this Act elements to assure safe use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) ELEMENTS OF STRATEGY; ENFORCEMENT.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

(A) is deemed to consist of the timetable required under section 505–1(d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and

(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505–1.

(3) SUBMISSION.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk

evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.

Subtitle B—Other Provisions to Ensure Drug Safety and Surveillance

SEC. 911. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS.

''(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. Such guidance shall indicate the appropriate models and valid surrogate markers.

''(b) REVIEW.—Not later than 5 years after the date of the enactment of this section, the Secretary shall review and update the guidance described under subsection (a) to reflect developments in scientific and medical information and technology.''.

SEC. 912. PROHIBITION AGAINST FOOD TO WHICH DRUGS OR BIOLOGICAL PRODUCTS HAVE BEEN ADDED.

(a) PROHIBITION.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 901(d), is amended by adding at the end the following:

''(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

''(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

''(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

''(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

''(A) a regulation issued under section 409 prescribing conditions of safe use in food;

''(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

''(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

''(D) a food contact substance notification that is effective under section 409(h); or

''(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

''(4) the drug is a new animal drug whose use is not unsafe under section 512.''.

(b) CONFORMING CHANGES.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 304(a)(1), by striking ''section 404 or 505'' and inserting ''section 301(ll), 404, or 505''; and

(2) in section 801(a), by striking ''is adulterated, misbranded, or in violation of section 505,'' and inserting ''is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll),''.

SEC. 913. ASSURING PHARMACEUTICAL SAFETY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended in section 403, is amended by inserting after section 505C the following:

''SEC. 505D. PHARMACEUTICAL SECURITY.

''(a) IN GENERAL.—The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

''(b) STANDARDS DEVELOPMENT.—

''(1) IN GENERAL.—The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

''(2) STANDARDIZED NUMERAL IDENTIFIER.—Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

''(3) PROMISING TECHNOLOGIES.—The standards developed under this subsection shall address promising technologies, which may include—

''(A) radio frequency identification technology;

''(B) nanotechnology;

''(C) encryption technologies; and

''(D) other track-and-trace or authentication technologies.

''(4) INTERAGENCY COLLABORATION.—In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

''(A) the Department of Justice;

''(B) the Department of Homeland Security;

''(C) the Department of Commerce; and

''(D) other appropriate Federal and State agencies.

''(c) INSPECTION AND ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this Act to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

''(2) ACTIVITIES.—The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

''(d) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b)(1).''.

SEC. 914. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 901(a), is amended by adding at the end the following:

''(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

''(1) IN GENERAL.—

''(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

''(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

''(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

''(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

''(i) Notification of the fact that a determination under subparagraph (A) has been made.

''(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

''(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

''(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

''(i) a document; or

''(ii) a meeting with the applicant involved.

''(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

''(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

''(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

''(i) any determination made under subparagraph (A);

''(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

''(iii) the consent of the petitioner.

''(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

''(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.', with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

''(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.', with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

''(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

''(A) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

''(i) during the 180-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

''(ii) such period expires without the Secretary having made such a final decision.

''(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

''(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

''(i) the petition filed under paragraph (1) and any supplements and comments thereto;

''(ii) the Secretary's response to such petition, if issued; and

''(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

''(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications that were approved during the preceding 12-month period;

''(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

''(C) the number of days by which such applications were so delayed; and

''(D) the number of such petitions that were submitted during such period.

''(4) EXCEPTIONS.—This subsection does not apply to—

''(A) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

''(B) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(5) DEFINITIONS.—

''(A) APPLICATION.—For purposes of this subsection, the term 'application' means an application submitted under subsection (b)(2) or (j).

''(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term 'petition' means a request described in paragraph (1)(A)(i).''.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on ways to encourage the early submission of petitions under section 505(q), as added by subsection (a).

SEC. 915. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 914(a), is amended by adding at the end the following:

''(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

''(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

''(B) improves communication of drug safety information to patients and providers.

''(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

''(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

''(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

''(i) patient labeling and patient packaging inserts;

''(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

''(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

''(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

''(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

''(vi) guidance documents and regulations related to drug safety; and

''(vii) other material determined appropriate by the Secretary;

''(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

''(D) preparing, by 18 months after approval of a drug or after use of the drug by 10,000 individuals, whichever is later, a summary analysis of the adverse drug reaction reports received for the drug, including identification of any new risks not previously identified, potential new risks, or known risks reported in unusual number;

''(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

''(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

''(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

''(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

''(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public

and private entities to fulfill the requirements of this subsection.

''(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.''.

SEC. 916. ACTION PACKAGE FOR APPROVAL.

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by—

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking ''(l) Safety and'' and inserting ''(l)(1) Safety and''; and

(3) adding at the end the following:

''(2) ACTION PACKAGE FOR APPROVAL.—

''(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

''(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

''(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

''(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

''(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

''(i) Documents generated by the Food and Drug Administration related to review of the application.

''(ii) Documents pertaining to the format and content of the application generated during drug development.

''(iii) Labeling submitted by the applicant.

''(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

''(v) The Division Director and Office Director's decision document which includes—

''(I) a brief statement of concurrence with the summary review;

''(II) a separate review or addendum to the review if disagreeing with the summary review; and

''(III) a separate review or addendum to the review to add further analysis.

''(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

''(I) participated in the decision to approve the application; and

''(II) consents to have his or her name included in the package.

''(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

''(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.''.

SEC. 917. RISK COMMUNICATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by section 603, is amended by adding at the end the following:

''SEC. 567. RISK COMMUNICATION.

''(a) ADVISORY COMMITTEE ON RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the 'Advisory Committee on Risk Communication' (referred to in this section as the 'Committee').

''(2) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

''(3) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

''(4) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

''(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

''(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

''(A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and

''(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.''.

SEC. 918. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 915, is further amended by adding at the end the following:

''(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

''(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

''(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.''.

SEC. 919. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public''.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described under such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under section 505–1(c)(2) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for post-approval safety with respect to the drug work together to assess, implement, and ensure compliance with the requirements of such section 505–1.

SEC. 920. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 918, is further amended by adding at the end the following:

''(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—

''(A) PUBLICATION.—The Commissioner shall—

''(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

''(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

''(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

''(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

''(3) AUTHORIZED GENERIC DRUG.—In this section, the term 'authorized generic drug' means a listed drug (as that term is used in subsection (j)) that—

''(A) has been approved under subsection (c); and

''(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.''.

SEC. 921. ADVERSE DRUG REACTION REPORTS AND POSTMARKET SAFETY.

Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 905, is amended by adding at the end the following:

''(5) The Secretary shall—

''(A) conduct regular, bi-weekly screening of the Adverse Event Reporting System database and post a quarterly report on the

Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter;

''(B) report to Congress not later than 2 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007 on procedures and processes of the Food and Drug Administration for addressing ongoing post market safety issues identified by the Office of Surveillance and Epidemiology and how recommendations of the Office of Surveillance and Epidemiology are handled within the agency; and

''(C) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments.''.

TITLE X—FOOD SAFETY

SEC. 1001. FINDINGS.

Congress finds that—

(1) the safety and integrity of the United States food supply are vital to public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination;

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) according to the Economic Research Service of the Department of Agriculture, the United States is increasing the amount of food that it imports such that—

(A) from 2003 to 2007, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average American diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat, and 78.6 percent of fish and shellfish; and

(5) the number of full-time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. 1002. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary''), in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) ingredient standards and definitions with respect to pet food;

(2) processing standards for pet food; and

(3) updated standards for the labeling of pet food that include nutritional and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) consider using surveillance and monitoring mechanisms similar to, or in coordination with, those used to monitor human or animal health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet of the Centers for Disease Control and Prevention, the Food Emergency Response Network of the Food and Drug Administration and the Department of Agriculture, and the National Animal Health Laboratory Network of the Department of Agriculture;

(2) consult with relevant professional associations and private sector veterinary hospitals;

(3) work with the National Companion Animal Surveillance Program, the Health Alert Network, or other notification networks as appropriate to inform veterinarians and relevant stakeholders during any recall of pet food; and

(4) use such information and conduct such other activities as the Secretary deems appropriate.

SEC. 1003. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled human and pet foods on the Internet Web site of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled pet foods, that is easily accessed and understood by the public.

SEC. 1004. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

SEC. 1005. REPORTABLE FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417) to provide the Food and Drug Administration the legal framework which is intended to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462) to establish a mandatory reporting system of serious adverse events for nonprescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act is intended to serve as an early warning system for potential public health issues associated with the use of these products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. REPORTABLE FOOD REGISTRY.

''(a) DEFINITIONS.—In this section:

''(1) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means a person that submits the registration under section 415(a) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held.

''(2) REPORTABLE FOOD.—The term 'reportable food' means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish within the Food and Drug Administration a Reportable Food Registry to which instances of reportable food may be submitted by the Food and Drug Administration after receipt of reports under subsection (d), via an electronic portal, from—

''(A) Federal, State, and local public health officials; or

''(B) responsible parties.

''(2) REVIEW BY SECRETARY.—The Secretary shall promptly review and assess the information submitted under paragraph (1) for the purposes of identifying reportable food, submitting entries to the Reportable Food Registry, acting under subsection (c), and exercising other existing food safety authorities under this Act to protect the public health.

''(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue, or cause to be issued, an alert or a notification with respect to a reportable food using information from the Reportable Food Registry as the Secretary deems necessary to protect the public health.

''(2) EFFECT.—Paragraph (1) shall not affect the authority of the Secretary to issue an alert or a notification under any other provision of this Act.

''(d) REPORTING AND NOTIFICATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food

is a reportable food, the responsible party shall—

''(A) submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) (except the elements described in paragraphs (8), (9), and (10) of such subsection); and

''(B) investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

''(2) NO REPORT REQUIRED.—A responsible party is not required to submit a report under paragraph (1) if—

''(A) the adulteration originated with the responsible party;

''(B) the responsible party detected the adulteration prior to any transfer to another person of such article of food; and

''(C) the responsible party—

''(i) corrected such adulteration; or

''(ii) destroyed or caused the destruction of such article of food.

''(3) REPORTS BY PUBLIC HEALTH OFFICIALS.—A Federal, State, or local public health official may submit a report about a reportable food to the Food and Drug Administration through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) that the official is able to provide.

''(4) REPORT NUMBER.—The Secretary shall ensure that, upon submission of a report under paragraph (1) or (3), a unique number is issued through the electronic portal established under subsection (b) to the person submitting such report, by which the Secretary is able to link reports about the reportable food submitted and amended under this subsection and identify the supply chain for such reportable food.

''(5) REVIEW.—The Secretary shall promptly review a report submitted under paragraph (1) or (3).

''(6) RESPONSE TO REPORT SUBMITTED BY A RESPONSIBLE PARTY.—After consultation with the responsible party that submitted a report under paragraph (1), the Secretary may require such responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, 1 or more of the following:

''(A) Amend the report submitted by the responsible party under paragraph (1) to include the data element described in subsection (e)(9).

''(B) Provide a notification—

''(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

''(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

''(iii) that includes—

''(I) the data elements described in subsection (e) that the Secretary deems necessary;

''(II) the actions described under paragraph (7) that the recipient of the notification shall perform, as required by the Secretary; and

''(III) any other information that the Secretary may require.

''(7) SUBSEQUENT REPORTS AND NOTIFICATIONS.—Except as provided in paragraph (8), the Secretary may require a responsible party to perform, as soon as practicable, but in no case later than a time specified by the Secretary, after the responsible party receives a notification under subparagraph (C) or paragraph (6)(B), 1 or more of the following:

''(A) Submit a report to the Food and Drug Administration through the electronic portal established under subsection (b) that includes those data elements described in subsection (e) and other information that the Secretary deems necessary.

''(B) Investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

''(C) Provide a notification—

''(i) to the immediate previous source of the article of food, if the Secretary deems necessary;

''(ii) to the immediate subsequent recipient of the article of food, if the Secretary deems necessary; and

''(iii) that includes—

''(I) the data elements described in subsection (e) that the Secretary deems necessary;

''(II) the actions described under this paragraph that the recipient of the notification shall perform, as required by the Secretary; and

''(III) any other information that the Secretary may require.

''(8) AMENDED REPORT.—If a responsible party receives a notification under paragraph (6)(B) or paragraph (7)(C) with respect to an article of food after the responsible party has submitted a report to the Food and Drug Administration under paragraph (1) with respect to such article of food—

''(A) the responsible party is not required to submit an additional report or make a notification under paragraph (7); and

''(B) the responsible party shall amend the report submitted by the responsible party under paragraph (1) to include the data elements described in paragraph (9), and, with respect to both such notification and such report, paragraph (11) of subsection (e).

''(e) DATA ELEMENTS.—The data elements described in this subsection are the following:

''(1) The registration numbers of the responsible party under section 415(a)(3).

''(2) The date on which an article of food was determined to be a reportable food.

''(3) A description of the article of food including the quantity or amount.

''(4) The extent and nature of the adulteration.

''(5) If the adulteration of the article of food may have originated with the responsible party, the results of the investigation required under paragraph (1)(B) or (7)(B) of subsection (d), as applicable and when known.

''(6) The disposition of the article of food, when known.

''(7) Product information typically found on packaging including product codes, use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food.

''(8) Contact information for the responsible party.

''(9) The contact information for parties directly linked in the supply chain and notified under paragraph (6)(B) or (7)(C) of subsection (d), as applicable.

''(10) The information required by the Secretary to be included in a notification provided by the responsible party involved under paragraph (6)(B) or (7)(C) of subsection (d) or required in a report under subsection (d)(7)(A).

''(11) The unique number described in subsection (d)(4).

''(f) COORDINATION OF FEDERAL, STATE, AND LOCAL EFFORTS.—

''(1) DEPARTMENT OF AGRICULTURE.—In implementing this section, the Secretary shall—

''(A) share information and coordinate regulatory efforts with the Department of Agriculture; and

''(B) if the Secretary receives a report submitted about a food within the jurisdiction of the Department of Agriculture, promptly provide such report to the Department of Agriculture.

''(2) STATES AND LOCALITIES.—In implementing this section, the Secretary shall work with the State and local public health officials to share information and coordinate regulatory efforts, in order to—

''(A) help to ensure coverage of the safety of the food supply chain, including those food establishments regulated by the States and localities that are not required to register under section 415; and

''(B) reduce duplicative regulatory efforts.

''(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible party shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section for 2 years. A responsible party shall, at the request of the Secretary, permit inspection of such records as provided for section 414.

''(h) REQUEST FOR INFORMATION.—Except as provided by section 415(a)(4), section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Reportable Food Registry.

''(i) SAFETY REPORT.—A report or notification under subsection (d) shall be considered to be a safety report under section 756 and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report or the notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

''(j) ADMISSION.—A report or notification under this section shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness.

''(k) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (d), the Secretary believes such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make relevant information from the Reportable Food Registry available to the Secretary of Homeland Security.''.

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ''section 201(g)'' and inserting ''sections 201(g) and 417''.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 912, is further amended—

(1) in subsection (e), by—

(A) striking ''414,'' and inserting ''414, 417(g),''; and

(B) striking ''414(b)'' and inserting ''414(b), 417''; and

(2) by adding at the end the following:

''(mm) The failure to submit a report or provide a notification required under section 417(d).

''(nn) The falsification of a report or notification required under section 417(d).''.

(e) EFFECTIVE DATE.—The requirements of section 417(d) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 1 year after the date of the enactment of this Act.

(f) GUIDANCE.—Not later than 9 months after the date of the enactment of this Act, the Secretary shall issue a guidance to industry about submitting reports to the electronic portal established under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section) and providing notifications to other persons in the supply chain of an article of food under such section 417.

(g) EFFECT.—Nothing in this title, or an amendment made by this title, shall be construed to alter the jurisdiction between the

Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.

SEC. 1006. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—The Secretary is authorized to enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood.

SEC. 1007. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

SEC. 1008. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) Congress should work to develop a comprehensive response to the issue of food safety.

SEC. 1009. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. 1010. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner of Food and Drugs shall annually submit to Congress and publish on the Internet Web site of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SEC. 1011. RULE OF CONSTRUCTION.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417); or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462).

TITLE XI—OTHER PROVISIONS

Subtitle A—In General

SEC. 1101. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by section 701, is further amended by adding at the end the following:

''SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

''(a) DEFINITION.—In this section, the term 'article' means a paper, poster, abstract, book, book chapter, or other published writing.

''(b) POLICIES.—The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

''(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is directed by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

''(d) TIMING FOR REVIEW AND CLEARANCE.—The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

''(e) NON-TIMELY REVIEW.—If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

''(f) EFFECT.—Nothing in this section shall be construed as affecting any restrictions on such publication or presentation provided by other provisions of law.''.

SEC. 1102. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

''(2) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.

''(3) TROPICAL DISEASE.—The term 'tropical disease' means any of the following:

''(A) Tuberculosis.

''(B) Malaria.

''(C) Blinding trachoma.

''(D) Buruli Ulcer.

''(E) Cholera.

''(F) Dengue/dengue haemorrhagic fever.

''(G) Dracunculiasis (guinea-worm disease).

''(H) Fascioliasis.

''(I) Human African trypanosomiasis.

''(J) Leishmaniasis.

''(K) Leprosy.

''(L) Lymphatic filariasis.

''(M) Onchocerciasis.

''(N) Schistosomiasis.

''(O) Soil transmitted helmithiasis.

''(P) Yaws.

''(Q) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary.

''(4) TROPICAL DISEASE PRODUCT APPLICATION.—The term 'tropical disease product application' means an application that—

''(A) is a human drug application as defined in section 735(1)—

''(i) for prevention or treatment of a tropical disease; and

''(ii) the Secretary deems eligible for priority review;

''(B) is approved after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

''(C) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health Service Act.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application.

''(3) LIMITATION.—

''(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to the date of the enactment of this section.

''(B) ONE-YEAR WAITING PERIOD.—The Secretary shall issue a priority review voucher to the sponsor of a tropical disease product no earlier than the date that is 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

''(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 365 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Services Act for which the priority review voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

''(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.''.

SEC. 1103. IMPROVING GENETIC TEST SAFETY AND QUALITY.

(a) REPORT.—If the Secretary's Advisory Committee on Genetics, Health, and Society does not complete and submit the Regulatory Oversight of Genetic/Genomic Testing Report & Action Recommendations to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') by July of 2008, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetics, Health, and Society and other groups and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring Federal efforts with respect to regulatory oversight of genetic tests to cease or be limited or delayed pending completion of the report by the Secretary's Advisory Committee on Genetics, Health, and Society or the Institute of Medicine.

SEC. 1104. NIH TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C–2(j)(3)(B), by striking ''section 319C–1(h)'' and inserting ''section 319C–1(i)'';

(2) in section 402(b)(4), by inserting ''minority and other'' after ''reducing'';

(3) in section 403(a)(4)(C)(iv)(III), by inserting ''and postdoctoral training funded through research grants'' before the semicolon;

(4) by designating the second section 403C (relating to the drug diethylstilbestrol) as section 403D; and

(5) in section 403C(a)—

(A) in the matter preceding paragraph (1)—

(i) by inserting ''graduate students supported by the National Institutes of Health'' after ''with respect to''; and

(ii) by deleting ''each degree-granting program'';

(B) in paragraph (1), by inserting ''such'' after ''percentage of''; and

(C) in paragraph (2), by inserting ''(not including any leaves of absence)'' after ''average time''.

SEC. 1105. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.

Subtitle B—Antibiotic Access and Innovation

SEC. 1111. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

(a) DEFINITION.—In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs, shall identify (where such information is reasonably available) and periodically update clinically susceptible concentrations.

(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available, such as by posting on the Internet, not later than 30 days after the date of identification and any update under this section.

(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

SEC. 1112. ORPHAN ANTIBIOTIC DRUGS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting regarding which serious and life threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under section 5(a) of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years 2008 through 2012.''.

SEC. 1113. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by

section 920, is further amended by adding at the end the following:

''(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

''(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

''(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

''(ii) the application submitted under subsection (b) for such non-racemic drug—

''(I) includes full reports of new clinical investigations (other than bioavailability studies)—

''(aa) necessary for the approval of the application under subsections (c) and (d); and

''(bb) conducted or sponsored by the applicant; and

''(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

''(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

''(i) in a therapeutic category in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved.

''(2) LIMITATION.—

''(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

''(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

''(3) DEFINITION.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

''(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

''(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2012.''.

SEC. 1114. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. DINGELL) and the gentleman from Texas (Mr. BARTON) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to include extraneous matter on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, I rise today to express strong support for H.R. 3580, the Food and Drug Administration Amendments Act of 2007. This is excellent legislation. It contains needed reforms to strengthen the safety of our Nation's drug, device, and food supply.

I want to pay a word of compliment to my Republican colleagues and say that we have come to a compromise which I believe is satisfactory in the broad public interest and is an excellent piece of legislation. And I want to commend my friend Mr. BARTON and our Republican colleagues for having worked with us well on this matter.

On July 11, 2007, the House passed H.R. 2900, the Food and Drug Administration Amendments, by a bipartisan vote of 403–16. The bill was hailed by all as a strong bill that would improve the lives of Americans by ensuring that drugs and devices are reviewed in a competent and in a timely fashion.

Earlier this year the Senate passed a similar bill. Since July, bipartisan meetings have been held frequently between the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor, and Pensions to reconcile the differences between the two bills.

This bill includes two very different user-fee programs, both vital to the timely approval of lifesaving drugs and devices. The legislation would significantly improve our postmarket safety programs, thereby preventing many of the drug and device injuries and deaths that occur today. It fills an important gap in therapies available to one of our most vulnerable and important patient groups: our children. Finally, I note that the period of market exclusivity in the pediatric studies remains 6 months, as in current law.

I want to thank all the members of the committee who have worked hard on this bill. They have endured long hours to ensure that this bill would be completed before the expiration of the two user-fee programs at the end of this month. And I want to pay particular tribute to the staff on both sides for their outstanding labors.

Mr. Speaker, I want to point out that if this bill does not pass in the time limits which are imposed upon us by the September 30 expiration of this statute, we will have significant problems here that we may not be able to address because, I would point out, that failure to do so will leave us with a situation where we are going to find that RIF notices will be going out at Food and Drug and the ability to approve new drugs will all of a sudden come to a screeching and unfortunate halt.

□ 1500

I urge my friends and colleagues to support this legislation; it is a good piece of legislation, it has the support of all who have worked with it, and I would commend it to the attention and the kindness of my colleagues.

Mr. Speaker, I reserve the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I yield myself such time as I may consume.

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. Mr. Speaker, most of us are too young to remember, but in the early days of the movies there was a series of movies based on the ''Perils of Pauline.'' Pauline was a heroine who always got tied to the railroad track, and just as the train was bearing down on her the hero would come out and rescue her for another adventure in the next movie reel.

Well, this bill before us has kind of experienced the Perils of Pauline. It started out in a tremendous positive bipartisan spirit here in the House. Chairman DINGELL and Subcommittee Chairman PALLONE on the majority and Mr. DEAL and myself on the minority side and our colleagues in the rank-and-file worked together. We reported a bill, and I don't remember how many votes it got on the House floor, but I believe it was over 400. It got over to the other body, and they modified it in some ways that were somewhat different than the House bill. The negotiations broke down, and it looked for a while this week that the Food and Drug Administration was going to have to send out reduction in force notices to over 2,000 employees at the Food and Drug Administration. But thanks to the tremendous leadership of Chairman DINGELL and Subcommittee Chairman PALLONE and the help of people like Congressman WAXMAN and others on the majority side, we've been able to come back together and create a unified House position and work with our friends in the other body. And they've accepted the compromise that's before us to say that here, at 3 o'clock on Wednesday afternoon, we're going to rescue Pauline and pass the PDUFA, I hope by unanimous consent on the suspension calendar, the PDUFA reauthorization bill, and lots of good things are going to happen.

I am honored to be the ranking member on the Energy and Commerce Committee, along with Subcommittee

Ranking Member DEAL, who has worked with the majority to put this compromise together.

I want to stress the sensitivity of completing the reauthorization of the Prescription Drug User Fee Program and the Medical Device User Fee Program right now. As I said earlier, if we were not to have done that by the end of this week, over 2,000 employees at the FDA would probably have received a reduction in force notice sometime next week or the week after. These are dedicated experts who are responsible for reviewing and approving new drugs, biologics and medical devices. If we were to lose those individuals, we would probably never get them back. That would have severe negative repercussions for everybody in this country.

The legislation before us will promote advancement in pediatric therapies both for pharmaceuticals and for medical devices. The Pediatric Rule and the Best Pharmaceuticals for Children Act have helped to fill a void in pediatric medicine. Prior to these acts, many children were not getting the best treatment because the information was simply not available to determine how a drug would act on them. Drugs do perform differently in different patients, which is especially true when that patient is a child. These acts have begun to provide physicians the information they need to make the best decisions for their pediatric patients. These two acts work together to ensure that accurate, timely pediatric use information is developed to ensure the best medical outcomes for the Nation's children.

The bill preserves the 6-month incentive that companies receive to do additional testing in pediatric populations. I want to emphasize that. The bill before us preserves the 6-month pediatric exclusivity provision in current law, and I think that's a real accomplishment. Chairman DINGELL should be commended for his leadership on that effort. I was glad to support him in that insistence on that particular provision. I would also like to thank Congresswoman ANNA ESHOO for her work on that provision.

Finally, the legislation addresses the issue of drug safety. No drug is completely safe. All drugs have some risk. The goal of the Food and Drug Administration is to ensure that the benefits of the drug outweigh any potential risks and ensure that patients have access to life-saving and life-improving medications.

The legislation before us today strives to ensure that the FDA has the authority to monitor drugs to ensure that the balance between the benefit and the risk remains in equilibrium. The FDA will now have the authority to require that drug sponsors conduct postmarket clinical trials. The FDA will now have the authority to require that a drug make a label change. The FDA will also now have the authority to impose additional requirements on a drug in the form of a risk evaluation and mitigation strategy when it is needed to ensure that a drug's benefits outweigh its risk.

Mr. Speaker, this bill is a bipartisan compromise that does strengthen the FDA, it will improve children's health, and it will reauthorize programs that are essential to ensuring that patients have timely access to drugs and medical devices.

Before I reserve the balance of my time, I again want to thank Chairman DINGELL, Subcommittee Chairman PALLONE, Ranking Member DEAL, and all the rank-and-file members. I also want to especially thank Ryan Long on the minority staff, the gentleman that is sitting to my left. He stayed up all last night working on these final nuances. I shouldn't say this, but I'm told that he has the same clothes on today that he had on yesterday because he has worked so hard on this bill. We do want to give him special commendation. And I would urge that he take the appropriate hygienic provisions as soon as possible.

With that, Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that I be permitted to yield the remainder of my time to the distinguished gentleman from New Jersey (Mr. PALLONE), the chairman of the subcommittee, and that he be permitted to control the time.

The SPEAKER pro tempore. Without objection, the gentleman from New Jersey is recognized.

There was no objection.

Mr. PALLONE. Thank you, Mr. Speaker, and I yield myself such time as I may consume.

Mr. Speaker, this is an important day for American consumers. Thanks to the legislation the House is about to pass, the Food and Drug Administration will have the financial resources and authorities necessary to ensure patients have timely access to safe and effective therapies.

First and foremost, this bill is about drug safety. In order to empower the FDA to protect the public from harmful drugs, we are giving the agency new authority to compel important labeling changes. This is a significant improvement over current policy, where FDA must haggle with drug companies and protracted negotiations that put patients and consumers at risk.

Under this bill, FDA will also be better equipped to force drug manufacturers to fulfill their responsibility to the American public and complete postmarket study commitments which are critical to ensuring a drug is safe.

In addition to these important new authorities, this bill authorizes the collection of $225 million in new user fees, a significant increase in the amount of funds dedicated for the use of drug safety activities.

The FDA Revitalization Act also provides for commonsense improvements to our Nation's food safety system, such as more stringent ingredient and labeling standards, establishment of an adulterated food registry, and improvements in public notifications.

Patients will be happy to know that the bill before us also requires greater transparency of drug makers by calling for clinical trials to be registered in a database monitored by the National Institutes of Health, along with basic results data. As we saw with the case of Avandia, making this information available to patients, providers and researchers is critical to uncovering potential harmful effects of a drug. And under this legislation, the public will also have greater access to internal documents that FDA used in its review of a drug application.

We also secure FDA scientists' right to publish by requiring the Secretary to establish clear policies on the timely clearance of articles written by FDA employees.

And finally, Mr. Speaker, this bill would make significant progress in reducing the number of conflicted experts who serve on advisory committees.

Mr. Speaker, I'm proud to say that this bill reauthorizes two very important programs for our Nation's children, the Best Pharmaceuticals for Children Act and the Pediatric Research and Equity Act. These programs have been crucial in the successful cultivation of important research used by doctors and parents to better determine what kinds of drug therapy is safest and most appropriate for a child patient.

In addition to the two existing programs, we're creating a new program that would help provide device manufacturers with greater incentives to conduct research and development of pediatric devices. Combined, these three bills will strengthen the research being done on pediatric uses of drugs and devices, and will make sure that our Nation's children have access to the medicines and therapies they need to grow up healthy and strong.

And finally, this bill reauthorizes two critically important user fee agreements with respect to prescription drugs and medical devices. These programs provide FDA with the necessary resources to review applications in a timely manner so patients who rely on new and improved drugs and devices don't have to go without. In addition to reauthorizing these existing user fee programs, this bill would establish a new user fee for the specific purpose of reviewing direct-to-consumer advertising.

I just want to commend Mr. DINGELL, our ranking member Mr. BARTON, Mr. DEAL, and all of the members here, Mr. WAXMAN, Ms. ESHOO, Mr. MARKEY. Their leadership on these issues has been unwavering. It is to their credit that we have a bill on the floor today.

This is a great victory for American consumers that will make tremendous strides in empowering the FDA and restoring public confidence in its ability to protect the public health, and I would urge my colleagues to vigorously support it.

Mr. Speaker, I reserve the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I would ask unanimous consent that the balance of the time on the minority side be yielded to Mr. NATHAN DEAL, the ranking member of the Health Subcommittee, for him to use and control as he sees fit.

The SPEAKER pro tempore. Without objection, the gentleman from Georgia is recognized.

There was no objection.

Mr. DEAL of Georgia. Thank you, Mr. Speaker.

I want to, first of all, thank Chairman DINGELL and Chairman PALLONE for working in a bipartisan fashion on this very important piece of legislation.

As we all know, the work of the FDA is vital to the health and safety of the citizens of this country, and especially legislation such as this that enhances their ability to deal with the questions of drug safety and the monitoring capabilities and the continuing programs that are so vital both to the drugs and to medical devices which require review and approval by the FDA.

The user fee programs that are being reauthorized by this legislation are very important to fulfilling their role in meeting their personnel needs to achieve a timely review of drugs and medical devices, and I believe that Congress should not and cannot afford to delay further action on this package. Certainly to do so would require FDA to begin to scale back their personnel, and none of us want to see that happen.

Moreover, patients demand and deserve to know that the medications they are taking are safe and effective, and that the FDA has adequate resources, both pre- and postmarket, in order to ensure that the safety of the Nation's drug supply is intact.

This legislation makes sensible bipartisan strides in that direction and balances the need to bring new life-saving medications to market, and at the same time provide the necessary protections for patient safety.

Like all compromises, there was a necessary give-and-take from all sides to bring this bill to the floor today. I think it is through the responsible work of the leadership of our committee of Energy and Commerce and through the processes that the committee has followed that we were able to accomplish that on this very significant piece of legislation.

I would urge my colleagues to vote in favor of the bill and hope that our colleagues across the rotunda would do likewise so that we can present a bill to the desk of the President for his signature which will keep this vital program and functions of FDA going forward and will not allow it to expire.

Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from California who has been a leader on this issue for so many years.

Mr. WAXMAN. Mr. Speaker, the legislation we are considering provides FDA with critical tools the agency has been desperately lacking in its efforts to protect the American public from unsafe drugs. This legislation will provide FDA with the ability to require companies to update their drug label with new information, and FDA won't have to haggle with companies to get them to make those changes.

It also says, in giving FDA this labeling change authority, Congress is making it clear that we do not intend to impact a drug company's responsibility to promptly update its label with safety information on its own accord.

The legislation also gives FDA the authority to require companies to conduct postmarket studies and clinical trials of drugs. And it creates a mandatory clinical trial registry and results database to increase the transparency of those trials.

□ 1515

Mr. Speaker, before we break our arms trying to pat ourselves on the back, I want to express my deep disappointment that today we are walking away from a critical opportunity to make some reasonable adjustments to the windfall profits that drug companies receive for conducting pediatric studies under the Best Pharmaceuticals for Children Act. This is not about whether those pediatric studies should be done. We all agree about that. They are being done now. There is no question they will continue to be done. But if we were to cut back slightly on the term of exclusivity for only the blockbuster drugs, that would make a great deal of difference to people who are paying the high cost for pharmaceuticals.

In my view, we lost that opportunity, and it is going to hurt a lot of our consumers. In my view, there is simply no justification for rewarding companies with incentives that are so far in excess of the actual cost of doing the studies themselves.

I am also deeply disturbed the legislation fails to remove the sunset on FDA's authority to require pediatric studies under the Pediatric Research and Equity Act. There is absolutely no reason Congress needs to keep revisiting this commonsense measure that allows FDA to get essential information about whether new therapies are safe and effective for children.

So although I am pleased that today will provide FDA with important new authorities and resources, I must express my deep regret that we fail to take this opportunity to help individuals, businesses, State governments and insurers who pay the bill for the higher prices that result when generic competition is delayed for these expensive blockbuster drugs. I think it is a shame. We are talking about drugs of $5 billion in sales a year. If they spend a couple million dollars for their studies, they are being overreimbursed at the consumer's expense.

Mr. DEAL of Georgia. Mr. Speaker, I have no other requested time and would be prepared to close whenever the gentleman from New Jersey is prepared.

Mr. PALLONE. Mr. Speaker, I yield 2½ minutes to the gentleman from Massachusetts who, again, had quite a bit to do with this legislation, particularly on the safety provisions.

Mr. MARKEY. First of all, I want to commend you, Mr. Chairman, and Chairman DINGELL, your staffs, Mr. WAXMAN, Ranking Member BARTON and Mr. DEAL, all the Members on the Republican side for the product that is here, all of the staff which has worked on it for so long. My own staff, Kate Bazinsky, who is sitting right here, just was married 2 months ago, this has definitely affected those first 2 months of marriage, the incredible negotiations that have taken place to reach this point, along with Mark Bayer who was working on the privacy parts of this legislation with your staffs. I congratulate everyone.

I am pleased that the final bill before us today retains the core drug safety and clinical trial provisions from the bill that Congressman WAXMAN and I introduced in March, which will improve transparency at the FDA and make drugs safer. Although I had hoped the sunset would be removed from the pediatric rule and less exclusivity given to blockbuster products under the pediatric incentive program, this bill is a historic achievement which will make drugs and medical devices safer for consumers around the world.

The past several years have been marked by drug scandal after drug scandal, Vioxx, Ketek, Paxil and Avandia. These drugs have harmed families across the country and come to symbolize the urgent need for reform at the FDA. Taking drugs should not be a game of RX roulette, and yet the FDA's current system is broken, and thousands of American families have been harmed by drugs with dangerous side effects.

Today, the House is responding to those failures. The bill is a victory for consumers and for patients. The bill will empower the FDA with important new authorities to mandate label changes and require postmarket studies. However, these new FDA authorities do not change the responsibility of companies to maintain drug labels and warn the public about risk.

For the first time ever, the FDA will have the power to impose civil monetary penalties on companies that fail to conduct required postmarket studies. It will also establish a new postmarket risk identification and analysis system to identify harmful side effects without compromising patient privacy.

Since 2004, I have been fighting for a mandatory clinical trial registry and results database which will ensure that the public has accurate and complete information about drugs and devices.

This bill will create that mandatory clinical trials database.

I am also extremely pleased that the FDA package includes language from the Markey-Rogers pediatric devices bill which is a major step forward for getting better and better devices for kids.

Mr. Speaker, again, I thank the chairman from New Jersey for all his great work.

Mr. PALLONE. Mr. Speaker, I would yield 3 minutes to the gentlewoman from California (Ms. ESHOO) and point out, again, her leadership on this issue, particularly with regard to children and the pediatric issues.

Ms. ESHOO. Mr. Speaker, I thank the distinguished chairman of the Health Subcommittee as well as all of my colleagues that have worked so hard to bring this bill forward. So I rise, obviously, in support of it because I think the bill is going to make an enormous difference in the safety and the effectiveness of drugs and medical devices used to treat adults and children.

I think the bill also strengthens the FDA. I think the American people want the FDA to be an agency that is strong in its protection of consumers around the country. We know that there have been shortcomings that have had terrible effects on many families in our country. So, I think this bill is a victory in that arena.

I am also pleased that the bill adopts much of my legislation relative to children and pharmaceutical drugs for children. The American Academy of Pediatrics has instructed us that only about 25 percent of drugs administered to children have been appropriately tested and labeled for use in kids. Pediatricians often had to prescribe adult pharmaceuticals for children by telling parents, ''cut the pill in half, cut it in thirds, cut it in quarters.'' We understood that we had to do better. By every measurement, the reauthorization of this legislation, previous legislation, was supported because it was very, very successful. We know that children are not small adults, and the legislation recognizes that. We have reauthorized, and we are doing the right thing.

I am pleased that the blockbuster provision is not a part of this legislation. The other body supported that. I didn't. This bill doesn't. In all negotiations, there is always give-and-take. There are items I supported that didn't make it into the package, including the permanent extension of the Pediatric Research Equity Act, which I championed, obviously, as part of my legislation in the original House bill. I hope that we can get to this at some point. I am sorry it is not in this bill.

Overall, I want to thank all of my colleagues that made this possible and that we are here today; certainly, Chairman DINGELL, Ranking Member BARTON, most especially the professional staff, because they do so much work, no one more than John Ford of our staff, and Virgil Miller. I would like to also thank Jennifer Nieto Carey, formerly of my staff, who worked so hard and extensively to help bring us to this point.

So this is a good bill. I think the whole House should support it. I think it is a tribute to the substance of it, that it is coming up under suspension. I salute everyone that made the effort a winning one. Most importantly, I think the bill is a winner for the people of our country, both children and adults.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Oregon (Ms. HOOLEY).

Ms. HOOLEY. Mr. Speaker, I would like to thank my colleague from New Jersey who has done a fabulous job of chairing the subcommittee.

Mr. Speaker, I rise today in strong support of H.R. 3580. Patients and consumers are the clear winners in this legislation today. This legislation will save lives by promoting the safe and quick approval of lifesaving medications and providing the FDA with vital new authority to protect consumers after a drug is on the market. This bill collects an additional $225 million over 5 years to enhance drug safety reviews and also promotes testing of pharmaceuticals and medical devices to ensure that they are safe for children.

Revisions I crafted with my colleague, Mr. DOYLE, the FDA and others require the creation of a unique device identification, or a UDI, system for medical devices that will help take important strides to improve the public health. Medical devices cannot easily be tracked or identified in any systemic fashion with current tools. A UDI system will enable the FDA to detect warning signs of a defective device earlier and quickly respond to recalls. Every person with an artificial knee, hip, pacemaker or any one of the thousands of other medical devices will benefit once this UDI system is in place.

Mr. Speaker, I urge my colleagues to support this bipartisan and comprehensive drug and device safety bill.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Illinois (Ms. SCHAKOWSKY).

Ms. SCHAKOWSKY. Mr. Speaker, I want to thank Chairman DINGELL and Chairman PALLONE, Mr. WAXMAN and Mr. MARKEY and Congresswoman ESHOO and all my colleagues on both sides of the aisle and their hardworking staffs for bringing this landmark bill to the floor today.

This bill strikes to the heart of some of FDA's most troubling issues by granting additional authorities to the Food and Drug Administration that are critical to enhancing drug safety. This bill gives consumers a larger role in deciding how user fees are spent to enhance drug safety, a huge victory for consumer protection. It will take steps to enhance the kind of information that will be available to patients and their families as they make personal decisions regarding their health care.

I am particularly pleased by the inclusion of an amendment I offered that will improve consumer's awareness of the MedWatch program, one of FDA's best but least known ways of monitoring adverse drug events once a product has been approved. Consumer reports of bad effects signal to FDA when prescription drugs pose a threat. The success of this program is crucial to postmarketing surveillance. Unfortunately, 9 out of 10 Americans are unaware that the MedWatch program exists, yet adverse drug and device reactions account for as many as 100,000 deaths every year.

My amendment requires that printed prescription drug ads include information on how to report side effects to the FDA's MedWatch program, both on the Internet and through a 1–800 number. It also requires the FDA to do a study on how we can best include this important information on the TV ads that have become so pervasive and influential in our society. So, again, I thank the chairman and staff for working with me to include this language.

This bill makes a strong statement about the importance of protecting people who rely on prescription medications to get through their day and remain active members of society. I am encouraged by the steps it takes toward a safer, more transparent Food and Drug Administration.

Mr. Speaker, I urge all my colleagues to support it.

Mr. DEAL of Georgia. Mr. Speaker, I have no other requests for time.

Mr. Speaker, I thank our staff and urge the adoption of this bill and I yield back the balance of our time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I just want to thank everyone, particularly the staff that were involved in putting this legislation together and all the negotiations. I want to thank our legislative counsel, Warren Burke, Energy and Commerce Republicans, Ryan Long and Nandan Kenkeremath; Mr. DEAL's staff, John Little; our Energy and Commerce Democrats, John Ford, Pete Goodloe, Virgil Miller, Bobby Clark; and Mr. WAXMAN's staff, Karen Nelson, Rachel Sher, Stephen Cha, Anne Witt; and also Mr. MARKEY's staffperson, Kate Bazinsky.

Needless to say, this bill is a product of a lot of hard work here in the House on both sides of the aisle, and, of course, we are also expecting, since this is going to be a consensus bill passed on the suspension list today, that it will pass easily in the Senate hopefully tonight or tomorrow. And it really addresses the problems and the safety issues that have come to light in the last few years.

□ 1530

I think many of us know there has been a lot of media attention to the fact that oftentimes drugs in the postmarketing situation have been problems. People have died. People have gotten sick. This bill I think effectively addresses those issues. I hope

and expect that it will be noticed, because it will make a difference in people's lives.

Mr. WAXMAN. Mr. Speaker, the legislation are poised to pass today provides FDA, for the first time, critical tools that the Agency has been desperately lacking in its efforts to protect the American public from unsafe drugs.

This legislation will provide FDA with the ability to require companies to update their drug label with new safety information. Our goal here is to address tragic situations like Vioxx. In that case, because FDA could not compel the company to promptly make a labeling change, the Agency haggled with the company for 14 months before consumers were finally warned about serious cardiac risks in the drug label. This is simply unacceptable.

However, this legislation will make clear that, in giving FDA this labeling change authority, Congress does not intend to impact, in any way, a drug company's responsibility to promptly update its label with safety information on its own accord. Under FDA's current regulations, companies are required to add new warnings to their labels as soon as they learn of new dangers, even if FDA has not yet required the change.

In promulgating those regulations, FDA made a sensible policy choice. FDA recognized that the companies themselves are in the best position to know about risks associated with their own drugs. Logically, then, the companies should also be charged with the duty to make consumers aware of a drug's risk at the earliest possible moment. FDA recognized that drug safety is first and foremost a shared responsibility between the Agency and the company. And, today, Congress is making it clear that we do not mean to disrupt that balance.

This legislation will also give FDA for the first time the authority to require companies to conduct post-market studies and clinical trials of drugs. Another section of the bill creates a mandatory clinical trial registry and results database to increase the transparency of those trials. Both of these provisions will make a critical contribution towards increasing the safety of our drugs once they are on the market.

But I want to express my deep disappointment that this legislation failed to adopt a compromise that would have provided consumers with much-needed relief from the ever-increasing cost of drugs. Today, we are walking away from a critical and very rare opportunity to make some reasonable adjustments to the windfall profits drug companies receive for conducting pediatric studies under the Best Pharmaceuticals for Children Act.

This is not about whether these pediatric studies should be done. We all agree about that. They are being done now. And there is no question that they would continue to be done if we were to cut back slightly on the term of exclusivity for just the blockbuster drugs that are realizing profits many times over the cost of doing pediatric studies. The Senate did this in its bill and I regret that the compromise agreement we are considering today did not reflect anything from the Senate approach on this issue.

In my view, there simply is no justification for rewarding companies with incentives that are far in excess of the actual costs of the studies themselves—often hundreds of times over.

I also am deeply disturbed that this legislation fails to remove what is an unprecedented sunset on FDA's statutory authority to require pediatric studies under the Pediatric Research and Equity Act. There is no reason Congress needs to keep revisiting this common sense measure that allows FDA to get critical information about whether new therapies are safe and effective for children—FDA quite obviously needs to have the ability to require that new treatments be tested in children. And there need not be any further discussion about that.

So, although I am pleased that we will provide FDA with critical new authorities and resources in this bill today, I must express my deep regret that we failed to take this opportunity to help individuals, businesses, State governments, and insurers who pay the bill for the higher prices that result when generic competition is delayed for these expensive, blockbuster drugs.

Mr. GENE GREEN of Texas. Mr. Speaker, I rise in strong support of this conference agreement to reauthorize important user fee programs at the Food and Drug Administration and enact critical drug safety reforms at the agency.

This legislation is the result of intense negotiations between the House and Senate, whose negotiators have worked tirelessly to reach consensus on this legislation. They did so with a looming deadline of September 31, after which the user fee program would expire and many hard-working FDA scientists would likely lose their jobs. To reach a compromise, all parties to the negotiation had to give and take, but I am pleased that the product before us represents something we can all support. I would like to congratulate the negotiators on their success.

The FDA Amendments Act of 2007 makes important changes at the FDA to place a greater emphasis on post-market surveillance within the agency. The Risk, Evaluation, and Mitigation Strategy established by this bill would give the agency the authority to monitor drugs throughout their life-cycle for adverse events or other signs of safety concerns. A critical aspect of this strategy is the additional authority this bill gives the Secretary of HHS to mandate that drug manufacturers conduct post-market studies.

Under this bill, the additional post-market activities extend to the user fee programs that help fund the drug approval process. Specifically, this bill directs drug manufacturers utilizing the FDA's drug approval process to dedicate an additional $225 million over 5 years for postmarket surveillance activities at the FDA. This additional funding represents an important investment by the pharmaceutical industry in the FDA's post-market safety activities, while also ensuring that pre-market user fees are adequate to bring potentially life-saving medicines to market in a reasonable time.

There is no question that the labeling and liability language prompted a great deal of debate during conference negotiations, but one thing is clear: the Congress in no way intends to limit the ability of a patient injured by a drug to seek redress from our Nation's justice system. FDA should have the ability to require labeling changes, but that additional authority does not absolve the drug manufacturer of any duty to initiate labeling changes on their own when new data bears out the need for a change. The implementation of stronger drug safety authorities does not mean that drug companies get a free pass when their products harm consumers. I am pleased that the conference agreement makes this point perfectly clear.

This legislation also reauthorizes the Medical Device User Fee Act, as well as the Best Pharmaceuticals For Children Act and the Pediatric Research Equity Act, which help ensure that pharmaceuticals are tested for their effect on children. After all, we know that children are not simply smaller adults, and part of protecting America's children is knowing how best to treat them when they face health concerns.

I would like to thank our Chairman, Mr. DINGELL, and our Health Subcommittee Chairman, Mr. PALLONE, for their work on this important legislation, and encourage my colleagues to support this important bill. These necessary changes at the FDA will go a long way toward restoring the American public's confidence in the agency and its ability to ensure the safety of the Nation's drug supply.

Ms. ESHOO. Mr. Speaker, I rise in support of H.R. 3580, the Food and Drug Administration Amendments Act.

This bill will make an enormous difference in the safety and effectiveness of drugs and medical devices used to treat adults and children.

I'm pleased that the bill adopts much of my legislation (H.R. 2589, Improving Pharmaceuticals for Children Act) to renew the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Together, BPCA and PREA represent two halves of a comprehensive effort to make sure that prescription drugs are appropriately tested and labeled for children.

According to the American Academy of Pediatrics, about 25 percent of drugs administered to children have been appropriately tested and labeled for use in kids. Pediatricians often have to prescribe drugs for ''off-label'' use, because the drug has not been studied in appropriate FDA-approved pediatric clinical trials. Children are not small adults; they have specific medical needs that have to be considered when drugs are used. Children have died or suffered serious side effects after taking drugs that were shown safe for use in adults but had different results in children.

The bill helps improve drug safety for children in two ways. First, under BPCA, the bill provides an incentive, an extra 6 months of marketing exclusivity, for a drug if the innovator company agrees to undertake comprehensive pediatric studies requested by the FDA. Second, under PREA, FDA is granted authority to require studies when there is a demonstrated need and drug companies are required to submit a pediatric assessment each time they apply to market a new drug or change an existing drug's indication.

I'm pleased this bill continues the BPCA incentive without the so-called ''blockbuster provision'' adopted by the Senate. The Senate's proposal would have reduced the incentive for drugs with annual sales of $1 billion, and, I believe the Senate language had the potential to kill ''the goose that laid the golden egg.'' The 6-month incentive has worked. According to GAO, 81 percent of the time FDA has offered this incentive for a drug, drug companies have accepted, undertaking studies that have generated pediatric data that would otherwise not have been available. Scaling back the incentive for ''blockbusters'' would risk that proven record of success. That is a gamble on the

health of children, and I'm pleased it's not in the bill.

In all negotiations there is give and take. There are items I supported that didn't make it into this package, including the permanent extension of PREA which I championed as part of my legislation and the original House bill. I hope we'll have a chance to revisit the issue in the next reauthorization, if not sooner.

On balance, this bill will make a huge improvement in the safety of drugs and devices. We should pass it and send it to the President today.

I want to commend Chairman DINGELL, Ranking Member BARTON and the professional staff of the House Energy and Commerce Committee, especially John Ford and Virgil Miller, as well as Jennifer Nieto Carey formerly of my staff, who worked extensively on this bill.

Mr. PALLONE. Mr. Speaker, I want to thank everyone again, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. DINGELL) that the House suspend the rules and pass the bill, H.R. 3580.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. PALLONE. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The vote was taken by electronic device, and there were—yeas 405, nays 7, not voting 20, as follows:

[Roll No. 885]

YEAS—405

Abercrombie
Ackerman
Aderholt
Akin
Alexander
Altmire
Arcuri
Baca
Bachmann
Bachus
Baird
Baker
Baldwin
Barrett (SC)
Barrow
Bartlett (MD)
Barton (TX)
Bean
Becerra
Berkley
Berman
Berry
Biggert
Bilbray
Bilirakis
Bishop (GA)
Bishop (NY)
Blackburn
Blumenauer
Bonner
Bono
Boozman
Boren
Boswell
Boucher
Boustany
Boyd (FL)
Boyda (KS)
Brady (PA)
Brady (TX)
Braley (IA)
Broun (GA)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Burgess
Burton (IN)
Butterfield
Buyer
Calvert
Camp (MI)
Campbell (CA)
Cannon
Capito
Capps
Capuano
Cardoza
Carnahan
Carson
Castle
Castor
Chabot
Chandler
Clarke
Clay
Cleaver
Clyburn
Coble
Cohen
Conaway
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crenshaw
Crowley
Cuellar
Culberson
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis (KY)
Davis, David
Davis, Lincoln
Davis, Tom
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dingell
Doggett
Donnelly
Doolittle
Doyle
Drake
Dreier
Edwards
Ehlers
Ellison
Ellsworth
Emanuel
Engel
English (PA)
Eshoo
Etheridge
Everett
Fallin
Farr
Fattah
Feeney
Ferguson
Filner
Forbes
Fortenberry
Fossella
Foxx
Frank (MA)
Franks (AZ)
Frelinghuysen
Gallegly
Garrett (NJ)
Gerlach
Giffords
Gilchrest
Gillibrand
Gingrey
Gohmert
Gonzalez
Goodlatte
Gordon
Graves
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Hare
Harman
Hastert
Hastings (FL)
Hastings (WA)
Hayes
Heller
Hensarling
Herger
Herseth Sandlin
Higgins
Hill
Hinojosa
Hirono
Hobson
Hodes
Hoekstra
Holden
Holt
Honda
Hooley
Hoyer
Hulshof
Hunter
Inglis (SC)
Inslee
Israel
Issa
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson (IL)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Jordan
Kagen
Kanjorski
Kaptur
Keller
Kennedy
Kildee
Kilpatrick
Kind
King (IA)
King (NY)
Kingston
Kirk
Klein (FL)
Kline (MN)
Knollenberg
Kuhl (NY)
LaHood
Lamborn
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lucas
Lungren, Daniel E.
Lynch
Mack
Mahoney (FL)
Maloney (NY)
Manzullo
Marchant
Markey
Marshall
Matheson
Matsui
McCarthy (CA)
McCarthy (NY)
McCaul (TX)
McCollum (MN)
McCrery
McDermott
McGovern
McHenry
McIntyre
McKeon
McMorris Rodgers
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Mica
Michaud
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murphy, Tim
Murtha
Musgrave
Myrick
Nadler
Napolitano
Neal (MA)
Neugebauer
Nunes
Oberstar
Obey
Olver
Pallone
Pascrell
Pastor
Payne
Pearce
Pence
Perlmutter
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts
Poe
Pomeroy
Porter
Price (GA)
Price (NC)
Pryce (OH)
Radanovich
Rahall
Ramstad
Rangel
Regula
Rehberg
Reichert
Renzi
Reyes
Reynolds
Richardson
Rodriguez
Rogers (AL)
Rogers (KY)
Rogers (MI)
Rohrabacher
Ros-Lehtinen
Roskam
Ross
Rothman
Roybal-Allard
Royce
Ruppersberger
Rush
Ryan (OH)
Ryan (WI)
Salazar
Sali
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Saxton
Schakowsky
Schiff
Schmidt
Schwartz
Scott (GA)
Scott (VA)
Sensenbrenner
Serrano
Sessions
Sestak
Shadegg
Shays
Shea-Porter
Sherman
Shimkus
Shuler
Shuster
Simpson
Sires
Skelton
Slaughter
Smith (NE)
Smith (NJ)
Smith (TX)
Smith (WA)
Snyder
Solis
Souder
Space
Spratt
Stark
Stearns
Stupak
Sullivan
Sutton
Tancredo
Tanner
Tauscher
Taylor
Terry
Thompson (CA)
Thompson (MS)
Thornberry
Tiahrt
Tiberi
Tierney
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Van Hollen
Velázquez
Visclosky
Walberg
Walden (OR)
Walsh (NY)
Walz (MN)
Wamp
Wasserman Schultz
Watson
Watt
Waxman
Weiner
Welch (VT)
Weldon (FL)
Weller
Westmoreland
Wexler
Whitfield
Wicker
Wilson (NM)
Wilson (OH)
Wilson (SC)
Wolf
Woolsey
Wu
Wynn
Yarmuth
Young (AK)
Young (FL)

NAYS—7

Duncan
Emerson
Flake
Goode
Hinchey
Kucinich
Paul

NOT VOTING—20

Allen
Andrews
Bishop (UT)
Blunt
Boehner
Cantor
Carney
Carter
Cole (OK)
Cubin
Davis, Jo Ann
Dicks
Granger
Jindal
Johnson (GA)
McCotter
McHugh
Ortiz
Putnam
Waters

□ 1555

Mr. GOODE changed his vote from ''yea'' to ''nay.''

Mr. PRICE of North Carolina changed his vote from ''nay'' to ''yea.''

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table

Stated for:

Mr. COLE of Oklahoma. Mr. Speaker, on Wednesday, September 19, 2007, I was unavoidably detained due to a prior obligation.

Had I been present and voting, I would have voted ''yea'' on rollcall No. 885.

INSURANCE CRISIS FACING HOMEOWNERS

(Ms. GINNY BROWN-WAITE of Florida asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. GINNY BROWN-WAITE of Florida. Mr. Speaker, after terrorists attacked New York City and Washington, DC on September 11, 2001, our Nation came together. Without a study commission or partisanship, Congress quickly passed the Terrorism Risk Insurance Act to help business owners, and acted swiftly again by passing an extension in 2005. Now again, less than 2 years later, we just considered another TRIA extension.

If Congress can come together and help businesses after a terrorist attack, we should be able to come together to help homeowners who cannot afford the skyrocketing costs of insurance. For over 3 years, Congress has forgotten about homeowners around the country who are grappling with ever-increasing insurance rates.

For these reasons, Mr. BUCHANAN and I offered an amendment in the Rules Committee that would have added homeowners' reinsurance as losses covered under TRIA. This measure would have helped new families, parents, and grandparents who are homeowners. Sadly, the Rules Committee did not allow this amendment to be part of the rule and so Members did not have the opportunity to help their constituents.

Although I voted for TRIA, we should be saddened that the majority chose only to help business owners today and to ignore the insurance crisis facing homeowners.

INJUSTICE IN JENA

(Ms. JACKSON-LEE of Texas asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. JACKSON-LEE of Texas. Mr. Speaker, tomorrow in Jena, Louisiana will be the culmination of the frustration and the outrage felt by so many

across America as relates to the Jena 6.

The Jena 6 is not about a few boys misbehaving, because we understand that when young people need correcting, we do so, but it is about the systemic discrimination, if you will, of African American males and Hispanic males as relates to the juvenile justice system. This young man should have been tried in the juvenile justice system, but he was tried in a system that gave him a sentence that was clearly, clearly without merit.

Tomorrow we go to ask for justice not just for this young man and the other five that are there, but for young men across America who have been discriminated against, not given a second chance, and using the justice system to punish on the basis of race or ethnic background.

Enough is enough. Where is the Department of Justice Civil Rights Division? Obviously, the lights are out. They need to turn their lights on.

□ 1600

SPECIAL ORDERS

The SPEAKER pro tempore (Mr. COURTNEY). Under the Speaker's announced policy of January 18, 2007, and under a previous order of the House, the following Members will be recognized for 5 minutes each.

GREEN BERET AND MEDAL OF HONOR HERO ROY BENAVIDEZ

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Texas (Mr. POE) is recognized for 5 minutes.

Mr. POE. Mr. Speaker, America is about people. Who we are and what we are is because of the people who have come to America. They are individuals who have lived and died and influenced the rest of us because of their tenacious spirit and determination.

Mr. Speaker, I am a history fan. I love American history especially, and Texas history, not the history of dates and movements, but the history of the lives of individual Americans who made a difference.

Roy Benavidez was one of those Americans. Roy Benavidez was born in South Texas in a small town called Cuero, August 5, 1935. He was the son of a sharecropper. He was an orphan and he had mixed blood of Yaqui Indian and Hispanic. He was raised by his uncle after he lost his family and he dropped out of school in the seventh grade. He didn't see the need for an education at that time.

He was a migrant farm worker. He worked all over Texas and as far as Colorado in the sugar beet fields and the cotton fields. He decided to join the United States Army in 1955, and he joined in Houston, Texas. He was in love with his hometown sweetheart, Lala Coy. So while he was away in Germany on active duty, he asked a local priest, his grandfather and his uncle if they would go to Lala's father and ask permission for Roy to marry her, and he agreed. Mr. Speaker, you have to appreciate that old school that marry this way.

While he was in the Army, however, he was in a lot of trouble, even though he was a member of the Military Police. So he finally joined the Special Forces training at Fort Bragg and reached the rank of staff sergeant and went to Vietnam as a Green Beret.

But on May 2, 1962, his life changed and the lives of many Americans changed. It is a story that is almost unbelievable. On the morning of May 2, 1968, a 12-man Special Forces team was inserted in Cambodia to observe a large-scale North Vietnamese troop movement, and they were discovered by the enemy.

Most of the team members were close friends of Roy Benavidez, who was the forward operating officer in Loc Ninh, Vietnam. Three helicopters were sent to rescue this 12-man team, but they were unable to land because of the heavy enemy concentration. When a second attempt was made to reach the stranded team, Benavidez jumped onboard one of the helicopters, armed only with a Bowie knife.

As the helicopters reached the landing zone, Benavidez realized the team members were likely too severely wounded to move to the helicopters. So by himself he ran through heavy small arms fire to the wounded soldiers. He was wounded himself in the leg, the face, and the head in the process.

He reorganized the team and signaled the helicopters to land. But despite his injuries, Benavidez was able to carry off half of the wounded men to the helicopters. He then collected the classified documents held by the now dead team leader. As he completed this task, he was wounded by an exploding grenade in the back and shot in the stomach. At that moment, the waiting helicopter's pilot was also mortally wounded, and that helicopter crashed.

He ran to collect the stunned crash survivors and form a perimeter. He directed air support, ordered another extraction attempt and was wounded again when shot in the thigh. At this point he was losing so much blood from his face wounds that his vision became blocked. Finally, another helicopter landed and as Benavidez carried a wounded friend to it, he was clubbed in the head with a rifle butt by an enemy soldier. That soldier bayonetted Benavidez twice.

Mr. Speaker, Benavidez was wounded in that one battle 37 times; seven gunshot wounds, he had mortar in his back, and two bayonet wounds. He was taken for dead and left for dead and zipped up in a body bag, but right before they zipped the bag up, he spit in the doctor's face, letting the doctor know he was yet alive.

He later recovered. He received the Distinguished Service Cross and then many years later Ronald Reagan presented him with the Congressional Medal of Honor. President Reagan stated that if this were a movie, no one would believe it because of the heroic deed of Roy Benavidez.

Mr. Speaker, after he retired from the military, Roy Benavidez went around America talking about the importance of an education, since he only went to the seventh grade. He talked to young gang members, he talked to youth, telling them to stay in school and get an education.

He was a remarkable individual. A Navy ship has been named after him, several elementary schools in Texas have been named after Roy Benavidez, and even a toy company has issued a Roy Benavidez GI Joe action figure.

Mr. Speaker, as we celebrate and honor Hispanic Heritage Month, one of those great Hispanic Americans was Roy Benavidez, a Texas hero, an American hero, a war hero that loved America and, as he said, got to live the American Dream the way that he wanted.

And that's just the way it is.

The SPEAKER pro tempore (Mr. SIRES). Under a previous order of the House, the gentleman from Maryland (Mr. CUMMINGS) is recognized for 5 minutes.

(Mr. CUMMINGS addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

IRAQI CIVILIAN DEATH TOLL

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Washington (Mr. MCDERMOTT) is recognized for 5 minutes.

Mr. MCDERMOTT. Mr. Speaker, we now know that the President intends to keep U.S. forces in Iraq throughout the remainder of his term and that he intends for the U.S. to perpetually occupy Iraq via massive and permanent military bases he has ordered built. We have just learned of the staggering loss of life as a result of this war.

According to a new and incredible study, the number of civilians killed in Iraq since the war began now exceeds 1 million Iraqi people. The Iraqi civilian death toll exceeds the death toll from the genocide in Rwanda. For years, we and others said we didn't know how bad it was in Rwanda. With this report, that excuse is no longer valid in Iraq.

The official death toll in Iraq, fewer than 100,000 is what the official number is, has long been considered fictitious by humanitarian and other international organizations. Now we are forced to confront evidence that puts the death toll above 1 million Iraqis.

Opinion Research Business, a respected and mainstream London-based research company that works for major corporations and government clients, including the U.K.'s Conservative Party, conducted the survey in August. I point this out to inoculate my colleagues, the media and the American

people from the venom that will spew from this for those who want to keep the real cost of this war in human lives as far from public view as possible, because no one who knows the truth could stand and let it go on.

Joshua Holland, a journalist at AlterNet, broke the news online the other day. I enter his story into the RECORD, which includes a link directly to the Opinion Research site where people can read the entire research survey online. It was conducted in 15 out of Iraq's 18 provinces during mid August.

In his speech last week, the President referred to Anbar Province as a model of success. The research company did not even visit Anbar or Karbala for security reasons. And they were not allowed to conduct their field research in Irbil.

While the President is willing to stand up and say that he sees signs of success, the survey found that in Baghdad alone, almost half the houses say they have lost at least one member of their family. That's the reality in the largest Iraqi city, which has the largest concentration of U.S. military forces. Baghdad may have a fortified green zone for U.S. diplomats and Iraqi government officials, but the rest of the people live in a bloody red zone, where the killing has claimed someone from 50 percent of the households.

The President cannot claim signs of success in Iraq when his stubborn determination to remain is dissolving Baghdad into a dead zone. The civilian carnage is not isolated in Baghdad. Other major cities also registered dramatic civilian murder rates that would make the world weep at the staggering loss of humanity occurring in Iraq.

For a long time, I and other Members have spoken out about the number of U.S. soldiers killed or gravely wounded in Iraq, and we must never forget the sacrifices made by American soldiers and the painful losses suffered by American families across this country. But Congress must not ignore the overwhelming loss of life in Iraq. News that 1 million Iraqi civilians have been killed should compel us to get the U.S. forces out of Iraq immediately.

I know and respect many of my Republican colleagues. Our politics may differ, but our principle to protect innocent people does not. How many more Iraqis must die? The carnage will continue as long as Republicans in Congress wear the blinders that the President hands out to enforce allegiance to his blind and bloody armed occupation in Iraq.

For the sake of humanity, remove the blinders and speak the truth to power. The Iraq war is a humanitarian catastrophe on a scale that exceeds the genocide in Rwanda. We claimed we didn't know about Rwanda. We can't claim that any more about Iraq

[From AlterNet, Sept. 17, 2007]

IRAQ DEATH TOLL RIVALS RWANDA GENOCIDE, CAMBODIAN KILLING FIELDS

(By Joshua Holland)

A new study estimates that 1.2 million Iraqis have met violent deaths since Bush and Cheney chose to invade.

According to a new study, 1.2 million Iraqis have met violent deaths since the 2003 invasion, the highest estimate of war-related fatalities yet. The study was done by the British polling firm ORB, which conducted face-to-face interviews with a sample of over 1,700 Iraqi adults in 15 of Iraq's 18 provinces. Two provinces—al-Anbar and Karbala—were too dangerous to canvas, and officials in a third, Irbil, didn't give the researchers a permit to do their work. The study's margin of error was plus-minus 2.4 percent. Field workers asked residents how many members of their own household had been killed since the invasion. More than one in five respondents said that at least one person in their home had been murdered since March of 2003. One in three Iraqis also said that at least some neighbors ''actually living on [their] street'' had fled the carnage, with around half of those having left the country.

In Baghdad, almost half of those interviewed reported at least one violent death in their household.

Before the study's release, the highest estimate of Iraqi deaths had been around 650,000 in the landmark Johns Hopkins' study published in the Lancet, a highly respected and peer-reviewed British medical journal. Unlike that study, which measured the difference in deaths from all causes during the first three years of the occupation with the mortality rate that existed prior to the invasion, the ORB poll looked only at deaths due to violence.

The poll's findings are in line with the rolling estimate maintained on the Just Foreign Policy website, based on the Johns Hopkins' data, that stands at just over 1 million Iraqis killed as of this writing.

These numbers suggest that the invasion and occupation of Iraq rivals the great crimes of the last century—the human toll exceeds the 800,000 to 900,000 believed killed in the Rwandan genocide in 1994, and is approaching the number (1.7 million) who died in Cambodia's infamous ''Killing Fields'' during the Khmer Rouge era of the 1970s.

While the stunning figures should play a major role in the debate over continuing the occupation, they probably won't. That's because there are three distinct versions of events in Iraq—the bloody criminal nightmare that the ''reality-based community'' has to grapple with, the picture the commercial media portrays and the war that the occupation's last supporters have conjured up out of thin air. Similarly, American discourse has also developed three different levels of Iraqi casualties. There's the approximately 1 million killed according to the best epidemiological research conducted by one of the world's most prestigious scientific institutions, there's the 75,000–80,000 (based on news reports) the Washington Post and other commercial media allow, and there's the clean and antiseptic blood-free war the administration claims to have fought (recall that they dismissed the Lancet findings out of hand and yet offered no numbers of their own). Here's the troubling thing, and one reason why opposition to the war isn't even more intense than it is: Americans were asked in an AP poll conducted earlier this year how many Iraqi civilians they thought had been killed as a result of the invasion and occupation, and the median answer they gave was 9,890. That's less than a third of the number of civilian deaths confirmed by U.N. monitors in 2006 alone.

Most of that disconnect is probably a result of American exceptionalism—the United States is, by definition, the good guy, and good guys don't launch wars of choice that result in over a million people being massacred. Never mind that that's exactly what the data show; acknowledging as much creates intolerable cognitive dissonance for most Americans, so as a nation, we won't.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Persons in the gallery must refrain from displays of approval or disapproval of the proceedings.

SHOULD WE BE SURPRISED? NOT REALLY

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Illinois (Mr. SHIMKUS) is recognized for 5 minutes.

Mr. SHIMKUS. Mr. Speaker, it is 4:10 and we have finished the work of today. Should I be surprised? I wish I wouldn't be surprised. I was going to give the new majority a chance to get their sea legs in about 6 months to manage the floor so that we would work throughout the day, but I continue to get disappointed at our early departure hours from the floor.

I have got numerous dates from throughout the year where we have stopped work: January 11 at 3:26 p.m.; 17 January, 5:52 p.m.; 23 January, 2:40 p.m.; 4:23 p.m., 2:44 p.m., 2:28 p.m., 4:58 p.m., 3:01 p.m., 2:51 p.m., 3:21, 3:46. Yesterday I think we left work at 3:30. Today we leave work at 4.

The problem, Mr. Speaker, is that just because we are here more days a week doesn't mean we are doing any more work. Many of us who would like to be home to visit with our constituents or be home to visit with our families would say let's work in the evening, let's work at 6 p.m., let's work at 7 p.m., let's go to 10 p.m. By golly, let's go to 11 o'clock at night. Let's be brave. Let's be courageous.

We know there are many issues that the American public want us to address. We heard the concern from my colleague just before. But where are we? We're done for the day. No more business. Now it is just Members coming to the floor and speaking what is on their mind. What is on my mind is we ought to be about the business that we are sent here to do.

I understand the new majority, and I wanted to cut them some slack on the first 6 months. Five days a week. Let's work. That's fine. But now we're past that time. Now we should be able to say: The days we are here in Washington, let's work. Let's start at 10, let's go to 6, let's go to 8, let's go to 10. Let's get our work done and then allow 435 Members to go back to their districts to do their town hall meetings, to visit with their constituents, to take care of the business.

Not only that, but most of us live at home. Most of our families live in the

districts we represent. We can't be good fathers, good mothers, good parents when we are stuck here at 4 p.m., 4:10, nothing else to do, just wait for the next workday to begin.

So, Mr. Speaker, my simple point is, if we are going to work here in Washington, can't we please go back to working in the evening? I don't think that is too much to ask for.

□ 1615

IN RECOGNITION OF ALAN KRUTCHKOFF AND THE ADOPT-A-SOLDIER PLATOON

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from New Jersey (Mr. ROTHMAN) is recognized for 5 minutes.

Mr. ROTHMAN. Mr. Speaker, I rise to recognize the Adopt-A-Soldier Platoon, Incorporated, their partners, Unilever and DHL, and in particular Mr. Alan Krutchkoff, the president and founder of the Adopt-A-Soldier Platoon and fellow resident of Fair Lawn, New Jersey.

Alan Krutchkoff started the Adopt-A-Soldier Platoon with one simple act of charity in April of 2003, when he discovered that the son of one of his wife's colleagues was being sent to Iraq as part of Operation Iraqi Freedom. Alan took the initiative to pair this young man with his friend and cofounder of the Adopt-A-Soldier Platoon, Mr. Holmes Brady, who had been a reservist with Special Forces. Alan and Holmes went shopping for supplies and sent a care package to the young man stationed in Iraq.

News of this act of kindness spread, and it wasn't long before Alan discovered that many of his coworkers at Unilever had relatives or friends serving overseas. And, thus, the idea of the Adopt-A-Soldier Platoon was born.

The people of the Adopt-A-Soldier Platoon have made many outstanding donations to our brave troops serving overseas. Their contributions include numerous care packages consisting of snack foods, soft drinks, books, movies and clothes, a custom-built giant video screen for a Super Bowl party, personal care items for female soldiers and 25,000 blank DVDs and camcorders which enable tens of thousands of our troops to make personal videos to send to their families during the holidays.

In their efforts to support our troops, the Adopt-A-Soldier Platoon has also gone well beyond simply sending care packages. In 2006, they worked with the chief information officer of the 10th Combat Support Hospital, which is the largest American military hospital in Iraq, to provide wireless Internet access for all of our soldiers. This provided the servicemen and women at the 10th CHS a closer connection to friends and family members and helped keep their morale high. The adoptee units of this exceptional volunteer group also includes the 412th Civil Affairs Battalion in Iraq, the 28th Combat Support Hospital in Baghdad, Logistics Support Area Anaconda where 25,000 Americans troops live, the 324th Integrated Theater Signal Battalion, and the 449th and 209th Aviation Support Battalions.

In addition to these activities, the extraordinary people of the Adopt-A-Soldier Platoon are supporting our soldiers in their mission to rebuild Iraq. They have partnered with Charlie Company, 412 Civil Affairs Battalion, in the al Anbar province to implement what is called Operation Hearts and Minds. This operation is aimed at helping Iraqi residents build schools and work on local infrastructure.

Supporters of the Adopt-A-Soldier Platoon at Unilever have also raised money to send soccer balls to local Iraqi children and to provide additional security equipment to strengthen military checkpoints.

I also want to draw particular attention to this group for their compassion. On June 6 this year, the Adopt-A-Soldier Platoon received a call from their contact at Charlie Company asking if they could help a sick Iraqi child get an operation in Jordan. Mariam, who was 1 year old, had a hole in her mouth and could not eat without getting sick. In one day, the people at the Adopt-A-Soldier Platoon raised $1,800 for Mariam's family to offset the costly medical and travel expenses she required.

Acts like this demonstrate the inherent kindness and generosity of Americans and, hopefully, generate much needed goodwill in Iraq.

Mr. Speaker, today it is my great honor to recognize the exceptional work of the Adopt-A-Soldier Platoon in supporting our troops; Unilever for their generous donations of products, money, and time; DHL for generously shipping care packages to Iraq; and, especially my friend and constituent, my fellow Fair Lawn resident, Alan Krutchkoff, for his tireless efforts and inspiring dedication to provide our men and women serving in the Middle East with a connection to their homes and families.

The organizations and individuals involved in this effort have greatly lifted the morale of tens of thousands of our troops who are putting their lives in harm's way tens of thousands of miles away from home, away from their families and friends.

This group of people, Mr. Speaker, is well deserved of every bit of recognition and praise we can impart upon them. I commend each and every person involved in this honorable effort, and hope that every Member of Congress will join me in recognizing the outstanding work of the Adopt-A-Soldier Platoon.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from North Carolina (Mr. JONES) is recognized for 5 minutes.

(Mr. JONES of North Carolina addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Texas (Mr. HENSARLING) is recognized for 5 minutes.

(Mr. HENSARLING addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

CONGRESSIONAL PROGRESSIVE CAUCUS AND THE OUT OF IRAQ CAUCUS

The SPEAKER pro tempore. Under a previous order of the House, the gentlewoman from California (Ms. WOOLSEY) is recognized for 5 minutes.

Ms. WOOLSEY. Mr. Speaker, the Congressional Progressive Caucus and the Out of Iraq Caucus sponsored a very important meeting this morning to review the dire situation in Iraq and to explore ways to end the occupation. At this event, we heard from Dr. William Polk, one of America's leading experts on the Middle East.

Dr. Polk taught Middle Eastern history, politics, and Arabic at Harvard before joining the U.S. State Department's Policy Planning Council responsible for the Middle East and responsible for North Africa. Later, he became professor of history and founding director of the Center for Middle Eastern Studies at the University of Chicago.

Dr. Polk is the author of many books, including the recently published book entitled, ''Violent Politics, a History of Insurgency, Terrorism, and Guerilla Warfare from the American Revolution to Iraq.'' To write the book, Dr. Polk studied insurgent movements throughout world history. He found that they were motivated by many different causes, including race, religion, culture, economics, and language, but he found that they all had one thing in common, an opposition to foreign occupation.

Dr. Polk's research has clear implications for our policy in Iraq. It tells us that the American occupation of Iraq can never solve the country's problems. Only the Iraqis can solve Iraqi problems. And it tells us that the only policy that now makes sense is to withdraw our troops in an orderly but rapid way, and couple that action with a carefully constructed program that will help the Iraqis to pick up the pieces and to rebuild their country with the help of the regional international community.

The lesson of history is clear, Mr. Speaker; yet, our leaders in the White House continue to follow a disastrous course of foreign occupation. Their blindness has put our Nation on a very dangerous course. The administration has called for an enduring relationship with Iraq, meaning many years, perhaps even decades, of American military involvement.

If the administration has its way, babies now in diapers will grow up and march off to Baghdad while the neocons who crafted our Iraq policy play golf in their retirement communities.

The administration's policy of endless occupation will cost us trillions of dollars and countless casualties. It will lead to the deaths of countless Iraqi civilians and surely force millions more to become refugees. Meanwhile, al Qaeda will continue to hatch its plots against the United States in their safe havens far from Iraq.

It is clear that Iraq will never stabilize and find peace while we are present. Our occupation of Iraq prevents Iraqis from finding solutions to their own problems, and it prevents the regional and international diplomacy that is absolutely needed to help them reconcile and to rebuild.

The timely withdrawal of American troops is the essential first step in solving the Iraqi problem. So long as our troops and military contractors are there, the situation can only and will only get worse.

In the days ahead, I and others will urge Congress to move to end the occupation. Congress has the power of the purse. We must pass a bill requiring that all spending related to Iraq be used for only one purpose, and that is to fully fund the safe, orderly, and responsible withdrawal of all American troops and military contractors.

If we fail to do this, we will have failed the American people, who sent us to Congress last November with a clear message: End the occupation of Iraq. And we will have failed our country morally, we will have failed our country politically, and certainly we will have failed it economically.

It is time, Mr. Speaker, to do what we know is right and what is best for our country: bring our troops home.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from North Carolina (Mr. ETHERIDGE) is recognized for 5 minutes.

(Mr. ETHERIDGE addressed the House. His remarks will appear hereafter in the Extensions of Remarks.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Indiana (Mr. BURTON) is recognized for 5 minutes.

(Mr. BURTON of Indiana addressed the House. His remarks will appear hereafter in the Extensions of Remarks.

The SPEAKER pro tempore. Under a previous order of the House, the gentlewoman from Ohio (Ms. KAPTUR) is recognized for 5 minutes.

(Ms. KAPTUR addressed the House. Her remarks will appear hereafter in the Extensions of Remarks.

MAJORITY MAKERS

The SPEAKER pro tempore. Under the Speaker's announced policy of January 18, 2007, the gentlewoman from Ohio (Ms. SUTTON) is recognized for 60 minutes as the designee of the majority leader.

Ms. SUTTON. Mr. Speaker, I would like to begin this hour by talking about a subject that has become one of the most significant issues of our time. I am going to be joined by members of the freshman class or the Majority Makers throughout this hour to talk about Iraq.

We have heard in recent days about what the President's idea of our way forward is. He has called for more money and more patience and a renewed commitment to U.S. troops in Iraq for the foreseeable future, another stay-the-course strategy that puts us on a path toward a $1 trillion, at least 10-year presence war in Iraq. On top of that, we have no convincing evidence that the political reconciliation necessary will be achieved even after so much sacrifice on the part of our brave troops will be realized.

I believe that the President's plan for Iraq amounts to an open-ended and dangerous commitment of American troops in Iraq and an open wallet from the American people to pay for it.

The question should not be whether we keep our troops in Iraq for 10 years. The question should be: How do we responsibly redeploy our troops? And how do we develop that plan that will do so while we continue to protect our homeland and fight against terrorists?

On August 19, we saw in the New York Times an editorial that was written by seven brave U.S. soldiers. I bring this to the attention, Mr. Speaker, of you and all those who may be tuned in because I think it is important that we listen to their vantage point. And while I won't be reading the entire article, I will read excerpts from it. Again, it is August 19, the New York Times, and I would suggest that everybody who can take a look at the complete editorial. It is entitled, ''The War As We Saw It.'' And it begins:

''Viewed from Iraq at the tail end of a 15-month deployment, the political debate in Washington is indeed surreal. Counterinsurgency is, by definition, a competition between insurgents and counterinsurgents for the control and support of a population.

□ 1630

To believe that Americans, with an occupying force that long ago outlived its reluctant welcome, can win over a recalcitrant local population and win this counterinsurgency is farfetched. As responsible infantrymen and noncommissioned officers with the 82nd Airborne Division soon heading back home, we are skeptical of recent press coverage portraying the conflict as increasingly manageable and feel it has neglected the mounting civil, political and social unrest we see every day.''

And then they say, in parentheses, ''Obviously these are our personal views and should not be seen as official within our chain of command.''

They continue:

''The claim that we are increasingly in control of the battlefields in Iraq is an assessment arrived at through a flawed, American-centered framework. Yes, we are militarily superior, but our successes are offset by some failures elsewhere. What soldiers call the 'battle space' remains the same, with changes only at the margins. It is crowded with actors who do not fit neatly into boxes: Sunni extremists, al Qaeda terrorists, Shiite militiamen, criminals and armed tribes. This situation is made more complex by the questionable loyalties and Janus-faced role of the Iraqi police and Iraqi army, which have been trained and armed at United States taxpayers' expense.''

And then they continue:

''Reports that a majority of Iraqi army commanders are now reliable partners can be considered only misleading rhetoric. The truth is that battalion commanders, even if well meaning, have little or no influence over the thousands of obstinate men under them in an incoherent chain of command who are really loyal only to their militias.''

They continue in this article, and they state, ''Political reconciliation in Iraq will occur, but not at our insistence or in ways that meet our benchmarks. It will happen on Iraqi terms when the reality on the battlefield is congruent with that in the political sphere. There will be no magnanimous solutions that please every party the way we expect, and there will be winners and losers. The choice that we have left is to decide which side we will take. Trying to please every party to this conflict, as we do now, will only ensure we are hated by all in the long run.''

These brave soldiers conclude this op-ed with the following:

''It would be prudent for us to increasingly let Iraqis take center stage in all matters, to come up with a nuanced policy in which we assist them from the margins but let them resolve their differences as they see fit. This suggestion is not meant to be defeatist, but rather to highlight our pursuit of incompatible policies to absurd ends without recognizing the incongruities.''

They say, ''We need not talk about our morale. As committed soldiers, we will see this mission through.''

I share that because I think it's worth having out there for our consideration and our contemplation to add to the wealth of information that is being presented to the American people.

I'm sad to report that since this oped began, they started writing this, during the course of writing it, one of these brave soldiers was shot in the head, and he is recovering. But on September 13, the headline in the same New York Times sadly stated, ''Skeptical But Loyal Soldiers Die in a Truck Crash in Iraq.'' And two of these soldiers who had the courage not only to go and fight for our Nation but to do everything they were asked to do were killed in Iraq.

We are here today to talk about this pressing, pressing issue. The light that

has been shed on this by these soldiers should be part of the discussion. I am joined here on the floor right now by a couple of my colleagues, leaders on this issue, I know, who feel it deeply. The gentleman from Florida, RON KLEIN, a tremendous new Member, at this point I am going to just yield to him for his remarks.

Mr. KLEIN of Florida. Thank you, Congresswoman SUTTON.

It's a pleasure to serve with you and the other 54 Members of our class. They call us freshmen. Some people call us freshmen. Some people call us majority makers. But clearly we're new Members, and I think that as new Members we probably have heard through some very active campaigns a very clear message from our communities and, that is, what's going on in Iraq, this is back in November, but continues to today, as your point is, is not working. And it's not working on a number of levels.

The way I sort of focus on this is the notion that all this should be about the national security of the American people. This is about what makes us safe in our homes, our communities, our States, our country. And yes, we obviously have interests around the world in other places as well. But first and foremost, what's important to us is at home, that we know our families and that we are protected.

The problem as I see it, and I think it has now been confirmed, and I'm on the Foreign Affairs Committee, so I've had the opportunity, as many of the Members of Congress have had, to get the briefings of a number of people, including members of the State Department and others, and we've all had the chance to go over and speak to the Joint Chiefs of Staff over at the Pentagon to get a firsthand question-and-answer about what the assumptions were in the surge and what the assumptions were in adding or subtracting military personnel and how our commitments were affecting the rest of our military and the rest of the commitments that we as Americans have internally. National Guard. I come from Florida. We have hurricane season, and are we at risk in terms of being able to respond, or anywhere in the world where our military is needed.

I think it's very clear, and I think most Americans understand this, that al Qaeda, Osama bin Laden, the people that perpetrated 9/11, it wasn't Iraq, it was Osama bin Laden and al Qaeda. Al Qaeda was not in Iraq at the time of September 11.

The bottom line is Osama bin Laden is still operating. Al Qaeda is still operating. And it's not operating in Baghdad. Sure there are cells in places in Iraq, and it's up to our military, and our military understands its responsibilities to root them out. Those are specific engagements and we should find those cells and root them out.

But al Qaeda is not limited to Iraq. They're operating in different parts of the world. Afghanistan is at a tipping point, as we understand it. Nobody, no Democrat or Republican, seems to be contesting that issue. Americans understand that the Taliban and al Qaeda are re-emerging in Afghanistan. Yet, our assets, our men, our women, our military hardware and equipment are saddled and stuck in Iraq. That's not to say that there's not a terrible situation in Iraq. It is a terrible situation.

But as Americans, we have to put ourselves first and say, what's in the best interest for America? Both here at home, and dealing with Afghanistan, dealing if there's a problem in Pakistan, dealing with Iran, dealing with North Korea. These are the potential hot spots around the world, where there are potential nuclear issues and things like that.

My biggest concern all along, and I know I share this with certainly all Members of our Democratic side, and I know many Republicans. This is not a Democrat-Republican issue. This is an American issue. It's what is the right thing to do. I think it's very clear, based on everything we've seen so far, is that this is not going to get resolved now, 6 months from now, a year from now, 5, 10 years from now, with just a military solution.

Senator LINDSAY GRAHAM, a Republican from the Carolinas, was before our Foreign Affairs Committee today, and he said he was there. He also specifically said, listen, our generals are generals. He comes from a military background. He did work in the legal corps of our military. He said, but, you know, generals are not always necessarily right. Ask them the tough questions. I know when General Petraeus came before our committee and many of us listened very carefully as to what he had to say, many of us were not quite fully satisfied that the answers were consistent. On the one hand he said, yeah, we're going to draw down. On the other hand he's saying, we need power, we need troops, we need, you know, the power to make sure that everything is there. It didn't all sound consistent to me.

But the bottom line is I think we need to be strategic and smart. And redeployment is not a question of getting everybody out immediately. Nobody is suggesting that among our group here today. What we are saying is be smart. Secure the borders. Do some things to make sure this doesn't spill out. Really double and triple our efforts to retrain the military, and there are other ideas not limited to anybody in this room. There are lots of generals out there, retired and active, that are coming up with good suggestions.

But repackaging the stay-the-course approach, which is what is going on right now, is not the answer. We need to have a better answer to protect our men and women in the field, and protect America most significantly, at home and abroad.

Ms. SUTTON. Thank you, Congressman KLEIN.

I couldn't agree more that we need to have that kind of a plan. And unfortunately, a plan for responsibly redeploying and a plan for dealing with the broad scope of protecting America and what's in America's best interest is not being offered up. In fact, it's not even being discussed, because we're having the same discussion that we've been having for years now about staying the course in Iraq.

I would like to shift it over to my colleague from New Hampshire, Representative CAROL SHEA-PORTER, who I know can shed a great deal of light on this as well as a member of the Armed Services Committee.

Ms. SHEA-PORTER. Thank you, Congresswoman.

I am on the Armed Services Committee and we've had many, many hearings on this issue. It has become very clear to me that we need a plan to redeploy responsibly and to start it immediately.

First, let's go over some of the facts once again because it is a national security issue here. There were no Iraqis on the plane that day. 9/11, there were no Iraqis. But we were attacked by people who had been trained in Afghanistan in Osama bin Laden's group, and we needed to go there. We needed to go to Afghanistan. We still need to win in Afghanistan. But somehow or another we got diverted to Iraq, and we have paid the price, and the Iraqis have paid the price as well.

We are now spending $10 billion a month, that we acknowledge, in Iraq. We really don't know the cost. We borrow money from Communist China to pay for this.

I was a military spouse and so I'm feeling particularly protective of our troops. Our soldiers are exhausted. We send the same team in over and over again. This is an American problem, not a Republican problem or a Democratic problem. It's an American problem, and it calls for an American solution.

Let us talk about what it looks like in Iraq right now. And I have been there. What it looks like right now, and it was the independent Jones report that verified this, and I appreciated the report very much, retired General Jones and his commission. What they talked about was 2.2 million Iraqis displaced within the borders of Iraq. Every single month for the past 6 months, 100,000 Iraqis have moved. They've left their homes, their communities, their jobs, if they had jobs, and they have moved.

Now, why would 100,000 people move? Because it's not safe. It's as simple as that. We've had ethnic cleansing there. If you look at the maps that was in the Jones Commission, 2005, you could see in the neighborhoods in Baghdad that they were mixed, Sunni and Shiia living side by side. By 2007, the mixed neighborhoods are virtually gone. They've had ethnic cleansing. They have militias.

People say, well, you know, take a look at this. The Sunnis have joined with the United States to defeat al

Qaeda. No, not really. What it is is an enemy of my enemy is a friend. What has happened here is that the Sunnis have joined with the U.S. right now so they can rid themselves of their enemies.

We estimate that al Qaeda is maybe 7 to 10 percent of the violence there. But the reality is that most of this violence is still a civil war. It comes from within and it has not gotten better.

We know that 95 percent of the children are showing terrible signs of posttraumatic stress syndrome disorder. We know that they have dirty water. We know that they have 2 hours of electricity if they're lucky.

We know that in every way to measure standard of life, it has declined. Why are we still there? That's the question that all of us are asking. Why are we still in Iraq? And why does the President have a plan that says, stay. Stay for how long? Just stay. That is not acceptable to the American public anymore.

I yield back to you and I thank you very much for bringing this to the floor today so that we can tell the American people what has really happened, what we have heard from independent commissions, and what the reality is for the people of Iraq and the people of the United States.

I would like to add one more point which is important. Let's look at the American benchmarks and let's ask where America is now. Where are we on education? Where are we on health care? Where are we on jobs? Where are we on infrastructure? We have poured so much money into Iraq. What about American benchmarks?

Ms. SUTTON. I thank the gentlewoman for her excellent remarks. I guess the question that comes to mind when you ask where are we on these domestic items, where are we going to be in 10 years on these domestic items?

At this point I would just like to shift it over to my great colleague, a new freshman Member, a majority maker who has brought a lot of valuable insight and knowledge to this body and on this subject, the Honorable JOE COURTNEY.

□ 1645

Mr. COURTNEY. Thank you, Congressman SUTTON, for yielding.

And I just want to follow up with my friend from the Armed Services Committee about the lack of strategic balance that presently is occurring right now in Iraq and Afghanistan. In late August, German authorities arrested three terrorists who were plotting a major attack on an American military installation in Germany. Where were they trained? Well, we know the answer. They were trained in northern Pakistan, in that region of the world where our own military and intelligence officials have identified the real threat to Europe and the U.S. in terms of where future hits are going to take place.

As a member of the Armed Services Committee, I was in Afghanistan in May. We had briefings from military commanders over there who have said that training camps are in full level of activity, and they made a flat prediction that we are going to see attempted attacks emanating from that region of the world.

Let's step back. We have 26,000 troops in Afghanistan; 165,000 troops in Iraq. Is this a strategy that is really aimed at what is in the national interest of this country? I mean obviously if we look at just recent events in terms of where arrests are taking place, where the real training is taking place to hit Europe and the U.S., the fact of the matter is it is in the northern part of Pakistan, which is an area that the Taliban is now pretty much able to move and operate unimpeded because we have a dysfunctional relationship with the Pakistani Government and the Afghan Government is too weak to basically police those borders.

And I think a lot of the debate that is taking place right now after the Petraeus-Crocker report, which is appropriately focused on whether or not the benchmarks that the Iraq Government set forth have been met and what is the level of wear and tear in terms of our Armed Forces, they are clearly important to discuss, but we also need to have an overall strategic vision about what is in the national interest of this country. And the fact is being involved at the level that we are at right now in a civil war in Iraq is not in America's national interest, and for the sake of our military families, as Congresswoman SHEA-PORTER indicated, and certainly for a safer, smarter foreign policy, we need to have a change in course and a redeployment.

Over the summer the New York Times did a study on the situation right now in terms of the mid-level officer corps of our Armed Services, our ground forces. In the 2001 graduating class from West Point, which just completed their 5-year tour of duty, 44 percent of the class have left the Armed Forces. That is the highest number in three decades. People need to think about that in terms of what is happening to the best and the brightest in our military. They are voting with their feet. They are leaving the armed services. And many commanders from the Vietnam era, General Shinseki being one of them, the Army chief of staff who had the wisdom and vision to predict that we would need hundreds of thousands of troops if we were going to truly police Iraq after Afghanistan, have spoken all across the country about the fact that what's happening in Iraq today is having the same effect, same negative effect, on our Armed Forces that the war in Vietnam had, which is a hollowed-out mid-level officer corps of our armed services. It took a generation to recover from that, and we are now seeing, with the exodus that is happening right now with, again, the best and brightest of our West Point graduates leaving our armed services, that we, for the sake of our own future, ground forces and military readiness, need to have a change of course in Iraq.

And Senator WEBB has an amendment that's coming up, the Dwell Time Amendment, which will require the Armed Forces by law to make sure that our Armed Forces have the same amount of dwell time as they do deployment. I think that is an important step. I am very excited that it looks like we are going to get to the 60-vote number in the Senate and overcome a cloture, that we are going to start bringing some sanity back into our military and defense policy so that we don't destroy the greatest warfighting machine in the world.

And I know Congressman WELCH from Vermont, my neighbor to the north and a good Red Sox fan, is also someone who has talked a lot about this issue in terms of the impact on our military families, and I would be happy to hear from Congressman WELCH from Vermont.

Mr. WELCH of Vermont. Thank you, Mr. COURTNEY.

Mr. Speaker, I don't think any of us want to be here talking about the war because it's a tragedy, and I believe the American people have come to that conclusion. Whether they supported going into the war or they opposed going into the war, they figured out that at this point our military men and women have done all they can do. They toppled Saddam. They reported back truthfully that there were no weapons of mass destruction, and they allowed stability in Iraq so that Iraq had three democratic elections. At a certain point, it is up to the Iraqis to step up and build their own institutions and their own democracy. We obviously can help and we have some responsibility. But the American people, those who supported the war, those who opposed going into the war initially, have come to a pretty commonsense conclusion: We have done our job, the military has performed ably, and it is time for the Iraqis to take our place.

The fundamental question that the President has put to this Congress and to the American people is this: Is it the proper role of the United States military to be refereeing a civil war? That's the question. Now, Republicans and Democrats in the past have been united that our military has a primary responsibility for defending us in fighting wars, not for refereeing civil wars.

A couple of things. One, there has never been an example in the history of the world where a third-party military has actually refereed a civil war to a peaceful political and economic conclusion. There are examples of third-party militaries, outside militaries, coming in on one side and, through force of arms, imposing an outcome. But that is not the policy even of the Bush administration.

Is this a civil war? Here's what is going on in Iraq right now: There are several different civil wars that are underway. In the south in the Basra region where our ally Great Britain has

basically taken its 44,000 troops down to 5,000 troops and redeployed them to a base, there are three different Shia wars going on. They're not fighting about democracy. They're not fighting pro- or anti-Iran primarily. They're not fighting about the future of Iraq as a united country. They are fighting about oil. It is about who is going to be in control of that port and that refinery in Basra.

You then go to Kurdistan. Kurdistan has been, in effect, independent since 1991, Mr. Speaker, after the first Gulf War. And they have actually built an economy. They have outside investment coming in. They will not even allow the Iraqi flag to be flown in Kurdistan and are bent on achieving their own independence. But they want oil as well and are threatening, and they have an independent military, the Peshmurga, to take significant forceful action if they don't, from their perspective, get their share of oil in the Kirkuk region.

Then you have Baghdad. Baghdad has been the site of the most extreme ethnic cleansing. Before the fall of Saddam, Baghdad had 65 percent population that was Sunni. That was the seat of Saddam's power. Now it is 75 percent Shia.

A neighborhood that I visited, Mr. COURTNEY, when I was with a delegation to Iraq, the Dora neighborhood, had previously been Sunni and was now Shia, and peace came about basically by displacing the people who used to be there and putting new people in.

And the overall dislocation in Iraq is astonishing, as you mentioned, my friend from New Hampshire: 2 million Iraqis displaced internally, 2 million exiled; 4 million people already, about 60,000 a month, are affected by this. And that is the equivalent in the United States, 20 percent of our population or about 50 million people. Think about it if 50 million people were displaced, either thrown out of the country or fleeing the country or had to move from Texas to Vermont or Vermont to New York because of force and fear.

Then you have the provinces around Baghdad. The Sunni Triangle, Anbar, Diyala, a couple of provinces where General Petraeus was arguing that there was, quote, ''progress.'' Well, again, no one is going to quibble about a military person's estimation of whether there is military progress, but what has happened there largely is that there has been dislocation. The Sunni tribal leaders have done what most analysts expected they would do: They would turn against al Qaeda because they are nationalists. They are much more concerned about Iraq than they are accommodating this radical ideology and they would, quote, ''work with the United States.''

But what's the price that we are paying? What is the tactical decision that was made? The decision was made to arm tribal chiefs. Now, that can work in the short run. It gives them arms to fight alongside American soldiers in some particular circumstances. But what is the overall policy of the Bush administration? It is a strong central Iraqi Government centered in Baghdad. So what you have now is a United States policy that arms factions in the provinces, which is a momentary truce of convenience, that has no loyalty to the central government in Baghdad. And down the road, as what happened in Afghanistan when the United States, to pursue its interest against the Soviet invasion of Afghanistan, armed the Taliban, and that Taliban then became the monster that produced an Osama bin Laden. But we have our policy where we are literally doing two things against the middle: arming factions who are hostile to a central government even as we say our goal is to have a strong central government.

So none of us know what all the details are, but what you have is an incredibly internal complexity: a Shia south where there is Shia factional fighting, a Sunni Triangle where there is a temporary alliance of convenience, you have ethnic cleansing in Baghdad, and you have a Kurdistan that is insisting upon being independent.

Incidentally, on this question of being independent, even the President's friends who have business interests are getting it. You read the report last week about Hunt Oil. Hunt Oil is owned by Mr. Hunt, a very good friend of the President, a big contributor and a member of the Foreign Policy Advisory Committee that the President pays deference to, listens to. Mr. Hunt bypassed the central government in Iraq and is entering into a direct oil agreement with Kurdistan. So he not only has made his bet that the President's policy is going to fail, he is making arrangements to profit by that failure.

So why is it that we are asking the American military, the American taxpayer to continue pursuing a dead-end policy? There is one reason that the President now offers to defend a policy that is bankrupt, that is a dead end, that has a history of failure. That argument that the administration is making is this: If we leave, there will be chaos.

Now, think about it. Those who oppose the war, those who voted against it argue that if we invaded Iraq, in all likelihood the outcome would be the quick toppling of Saddam and the long-term chaos and violence that would follow. The argument that the President rejected then he is embracing now.

All of us who oppose the war really do so with a heavy heart because we know that the choices that are available to this country and to the people of Iraq are very constrained and there is going to be untold suffering that lies ahead. We don't have good choices, but the question is what is the right choice that is going to mitigate the suffering? And that right choice has to be to redeploy our troops because the continued presence of the United States through the military emphasizes a military approach to a political problem. And that's why all of us are here doing everything we can to change our direction in Iraq.

And I thank you for my opportunity to participate with my wonderful colleagues.

Ms. SUTTON. Thank you, Congressman WELCH.

And we have been joined by another great new Member of the class and a great help on issues related to Iraq and so many more things, my colleague from the Rules Committee, the esteemed MIKE ARCURI.

I yield to Mr. ARCURI.

Mr. ARCURI. Mr. Speaker, I thank my friend and colleague from the great State of Ohio for organizing this and bringing us all together here, and I thank all of you for being here.

Like so many other Members of Congress, I have had an opportunity to go to Iraq. And recently I came back from there, about 3 weeks ago, and I couldn't help but be so impressed with the incredible job that our troops are doing there. The men and women that are there are doing everything that is asked of them and much more in an incredibly hostile environment.

□ 1700

And they're doing it not just as a job, but they're doing it with intensity and passion. And they're doing a great job at what they do in just incredibly hostile circumstances. I am convinced, after seeing the job that they did, that our military, in a just cause, could accomplish anything we ask of them, anything in the world. And I was just very impressed with how hard they're working.

But you can't help but be troubled by the fact that the mission there continues to change. I can't help but think about, the old example that they use in football is every time that the team sets up to kick a field goal they move the goalpost back. It just seems like that's what we're doing. First, as my friend from Vermont just said, we were told we were going to Iraq for weapons of mass destruction. That didn't pan out. We were told we had to remove a dictator in Saddam Hussein. Our soldiers did that, and they did it magnificently. Then we were told we had to stay until there were free elections. We had free elections. Then we were told that we had to stay there; in fact, we not only had to stay there, we had to increase our numbers there, we had to have a surge so that we could reduce the violence so that the government would have an opportunity, would have a chance to come together. And that's exactly what our soldiers did. And despite that fact, we are still told that we will continue to be there. This is just unimaginable.

Our soldiers have done everything that we have asked of them, and much more, in an incredibly hostile environment, and yet they continue to be told that they have to stay in Iraq. And for what?

I am convinced, after meeting with Dr. Salam al-Zubaie, the Deputy Prime Minister, that the factions in Iraq will continue to fight, they will continue to use America as a crutch for as long as they possibly can. We gave them time. We did exactly what we said we would do. And what did they do? They squandered that time. They continued to posture for a better position, and they continue to do that today. Blood is spilling, Iraqi blood, American blood, and they continue to posture. Violence increases, and they continue to posture. They refuse to come together. It is high time for us to allow Iraq to take over, to stand up for itself. They will stand up when we stand down.

The other thing that was very amazing, when you see it, and we talk about how much money we're spending there, we talk about the $16 million an hour, the $2 billion a week. And they sound like numbers until you actually go there and you see the amount of equipment and you see the amount of investment we are making there. And obviously that is something that we have been doing and we will continue to do. But when you think about the fights that we have here right on this floor, the debates that we have on this floor about things like SCHIP, about things like improving our infrastructure that's crumbling, about things that are good domestically for our economy, and we don't do them. And we discuss and continue to debate about the money, and yet we spend billions and billions of dollars in Iraq.

I think while we do that, countries like China continue to take money and they invest it in their economy. We need to make our investment in our domestic economy, in our bridges, in our infrastructure, in our economy, in our health care system, in education. Those are the things that the American people want. Those are the things that we ran on last year. Those are the things that we promised the American people. And those are the things that we need to continue to work on.

I thank you thank you very much, my colleagues from the freshman class, for being here today. And, Ms. SUTTON, thank you very much for bringing us here.

Ms. SUTTON. Thank you, Representative ARCURI. That firsthand account and your observations are very enlightening. We appreciate you bringing them forward and, again, highlighting the fact that as we make this choice and as the President opts to try and keep us in Iraq for 10 years, or beyond, it means there are other consequences. Beyond all of those other consequences we talked about militarily and the effects on our military, there are those domestic issues, Representative SHEA-PORTER, that you point out and Mr. ARCURI points out that we will continue to fall behind on. I think that the picture is becoming a little bit more clear down here tonight that we need some comprehensive thinking that is smart and effective. And the question of a responsible redeployment and what that plan should look like is really the one that we need to be working on.

With that, I want to pass it over to another great Member of the new Congress, a freshman from Minnesota who I think is going to shed some light on the Blackwater situation.

Mr. ELLISON. Mr. Speaker, I am really honored to join my members of this freshman class. I am so proud to be a Member of the 110th Congress.

I just wanted to point out that this week as we contemplate and as we've seen the three reports, the GAO report, the report from General Petraeus, the report from General Jones, we are at a point where we have to make a big decision. The people of America and Iraq want our troops to have a safe but clear end point to this conflict. The surge has not been successful, as we see 11 of 18 legislative security and economic benchmarks set down have not been met.

But I just wanted to talk about a very interesting and curious development in this whole conflict, which is that part of the story of the Iraq conflict is the contractors. Blackwater is the most well known of them, but that's not the only one. There's DynCorp, there's Titan, there's Casey, there's many of them. As a matter of fact, what we have seen is a privatization of this conflict. We've seen the privatization of this conflict as literally estimated at upwards of 150,000 contractors have been in Iraq. And the question is, since we've never privatized a war, since we've always kept an essential governmental function, which is defense of the Nation, within the firm hands of the government and we've never really privatized a military conflict before, what does all of this mean? Interestingly and sadly, we've seen this privatization situation devolve into a very dangerous situation which I believe has in many ways compromised national security and has damaged the reputation of the United States and has led, in my view, to a situation where the Iraqi Government, even though it is a government under occupation, under U.S. military occupation, has had to make a statement to throw Blackwater out of its country.

Now, think about that. This is a government that is not in full control of its own country but has mustered itself and said, Look, in order to go forward, this institution, Blackwater, must leave our country. I just want to talk about this a little bit because I think that it's an important part of the story and it needs to be told even from the floor of Congress.

The recent incident that I'm talking about has caused the Iraqi Government to revoke the license of Blackwater. This is the result of a situation, of a killing of Iraqi citizens that happened on September 11, 2007 and the wounding of 14 others by a Blackwater USA security company. Ostensibly, this private security company guards U.S. Embassy personnel in Iraq. Blackwater USA is based in North Carolina and is one of the largest of at least 28 different private security firms that have received governmental contracts to work in Iraq, paid for by at least $4 billion in taxpayer dollars.

This group, funded by American taxpayer dollars through their contract, seems to hold very few American values, it seems to me, except for making money, by some accounts as much as five times the amount that our brave soldiers make. Five times the amount the average soldier is making is what one of these contractors can make, particularly one that was in Blackwater. According to one source, in February 2004, Blackwater started training former Chilean commandos, some of whom were serving during the Pinochet years in Chile, for duty in Iraq. People who know the Pinochet regime know that this regime was known for people disappearing in the country. Torture was routine. Other news reports indicate that four of the guards killed in January while working for a subcontractor had served in South Africa's security forces during the apartheid era, and one of them had applied for amnesty for crimes that he committed while operating under the apartheid regime. Not good news.

Press reports further indicate that this latest incident was not isolated, with Iraqi Interior Minister spokesman Abdul-Karim Khalaf calling the episode the ''last and biggest mistake'' committed by Blackwater.

Khalaf went on to say, ''Security contracts do not allow them to shoot people randomly. They are here to protect personnel, not to shoot people without reason.''

Mr. Speaker, we are not in a position to win the hearts and minds of the Iraqi people if we have cowboy mercenary vigilantes. Blackwater seems to be accountable neither to the Iraqi Government, and there are serious questions as to whether they're even accountable to the U.S. Government. They are not subject to the Geneva Convention, which our soldiers are. If accounts of this and other incidents prove to be accurate, and of course due process is critically important, then the Iraqi Government's actions to expel Blackwater from Iraq could indicate the first concrete sign that a real government may exist in Baghdad. Who knows. We'll see.

Mr. Speaker, I think it is very critical that we continue to look into this issue of private contractors. It is an important part of the story of Iraq. It is a critical and fundamental part of this dialogue that we're having. We can't privatize our Nation's national defense. When we do, we lose control of these people.

Mercenary actions are not deemed sanctioned by U.N. charter. And to hire a private mercenary army is something that we should not be associated with. They call themselves security contractors, and yet they have been involved

in major military actions in Najaf. Everybody remembers the horrific incident that occurred in Fallujah that was succeeded by a major action against that city. At this point I think it's important for us to pay much closer attention to this situation and put some real accountability on this situation.

I yield back at this time, but I do ask that we raise these important issues and focus on exactly what this means for our country and our national security.

Ms. SUTTON. I thank Representative ELLISON for that addition to this debate this evening. It's important that all of this be exposed to the light of day so that we can make the inquiries that are appropriate as well as the policies that make sense from this Chamber.

At this point, I would like to throw it back over to Representative CAROL SHEA-PORTER from New Hampshire. I think, Representative SHEA-PORTER, you were going to share with us some statistics and information from a report.

Ms. SHEA-PORTER. Thank you, Congresswoman.

I am holding in my hands a report to Congress from September 6, 2007 called ''The Independent Commission Security Forces of Iraq.'' This is retired General Jones. They did an absolutely wonderful job, nonpartisan, and I'm very pleased to say that it seems incredibly accurate and fair in all respects.

Here is a concern, or one of the many concerns that I have, and I just want to read a couple of lines and talk about it. It says, Iraq's central government in Baghdad, and this is page 39, does not have national reach in terms of security, nor does it have a monopoly on use of force, a defining characteristic of a functioning nation state. Militias continue to play a prominent role and are seen by American and Iraqi officials alike as posing almost as significant a threat to Iraqi stability and security as al Qaeda in Iraq.

Now, isn't that fascinating? We hear them talk about al Qaeda, al Qaeda, al Qaeda in Iraq. Al Qaeda was not in Iraq on 9/11, 2001, and yet we have militias roaming around and there is very little talk about that.

Now, as this report states, if you have militias, it means that the Iraqi Central Government is not in control of their streets. This is where we have our soldiers, in the middle of a civil war. And this is the reason that we've had ethnic cleansing and the other problems that we're having.

I want to talk about the Iraqi political establishment for a moment. Our troops have done everything they've been asked to do. They are guarding the streets. And yes, violence has gone down where our troops are, and it's a great credit to our troops, but I can tell you right now that if you put 50 policemen and women on a corner of any major city in America, or anywhere, crime would go down because these forces do a terrific job, but it doesn't mean that you've changed the hearts and minds of the people, the criminals. What we have here is an Iraqi Government that has not stepped forward. And so we are relying on our troops to not only control the violence in Baghdad, but also to run everything.

The Iraqi Government, the Parliament, wanted to take 2 months off this summer in the middle of this crisis. When the White House, Tony Snow, was asked about the 2-month vacation, he said, well, it's 140 degrees there. And somebody said, well, aren't our troops in 140 degrees as well?

The Iraqi Parliament also, more than half of them, signed a petition asking the United States to leave Iraq. Now, this is not leadership. Our troops have waited for years for Iraqi leadership to step forward and run their country.

□ 1715

We cannot ask our troops to not only be the police there, be the cop on the beat there, but also to be the politicians there. If the Iraqi Government will not, cannot, step up, we have to finally say we have to step down. It has been just too long.

So picture that, what it is like, and you will understand why 100,000 Iraqis have been leaving every month and why there is more than 2 million people who are now out of the Iraqi borders. They have lost their middle class. They have lost anybody who could help the society. They have fled. And you understand why, when you think about militias and you think about the lack of Iraqi political leadership. You didn't hear very much about that coming out of the White House. Ask them to name the Iraqi politicians, the leaders, who are going to take over, and ask when. Because they can't say when. They can't name who is going to take over. We cannot leave our troops there indefinitely until the Iraqis decide to find political reconciliation.

That is the problem. As long as we have our troops there, yes, we can tamp down the violence where our troops are. But we must have a government. That report shows that they have militia wandering around and that the Iraqi Government has not stepped up to the task. We are in our fifth year, Americans know that, our fifth year of our treasure and our blood of our people. It is time to stop.

Ms. SUTTON. Well, I thank the gentlewoman from New Hampshire. It is a sad state of affairs, but it goes back to the point that we have heard here tonight, and that is that unity in Iraq, really, at the end of the day, is going to be determined by the people of Iraq. We all know that our military has performed valiantly and selflessly and that they are true American heroes. But as you point out, it is not fair to keep them trapped in the middle of a civil war and refuse to acknowledge that all that has been discussed here tonight is going on. That is not a prudent plan. I think it is time. We have heard the call when we go home and talk to our constituents. It is time for a plan to responsibly redeploy. That is what the American people need from our President.

I will share just a few statistics with you that sort of buttress this need. We know that there was a great rollout when we had this so-called surge introduced as a new way forward. But let me just shed some light on some of the results. In June, July and August of 2007, it marked the bloodiest summer so far U.S. troops in Iraq have had, with 264 soldiers killed. U.S. casualties in Iraq are 56 percent higher this year than they were at this time in 2006. Since January of this year, we have lost 761 brave servicemen and women to the war in Iraq.

By the way, I should say that these statistics are as of September 10. I have fear they have grown since then. As of September 10, 3,759 U.S. troops have been killed and more than 27,770 have been wounded in Iraq since it began in March 2003. Think about that. Think about the cost in lives. Think about the cost in the casualties and the injuries that our soldiers are facing for the rest of their lives in many cases, the costs to them, which is unfathomable and enormous, and the cost to the American people as we do what we must do, and that is provide them with the health care and the resources they need and to fulfill the promise that we make to them when we send them into harm's way. We must take care of our veterans.

We also learn that, and you pointed this out, Representative SHEA-PORTER, that in Iraq, opinions are also that they would like our troops to be responsibly deploying. Just to share some information from a new poll that was jointly conducted and released by ABC News, BBC News and Japan's NHK, 47 percent of Iraqis want American forces and their coalition allies to leave the country immediately. That is a 12 percent increase over March. Remember, our soldiers are there in that environment. The polls showed that every person interviewed in Baghdad and Anbar province, a Sunni-dominated area where Bush recently visited and cited progress, said the troop increase has worsened security. Seventy percent believe security has deteriorated in the areas where the U.S. surge troops were located. Between 67 and 70 percent say that the surge has hampered conditions for political dialogue, reconstruction and economic development. Fifty-seven percent of Iraqis say that attacking coalition forces is ''acceptable,'' more than three times higher than when polled in February of 2004. That is the environment we are keeping our troops in. The President's plan is to do so for the very foreseeable future.

It is time for a plan of responsible redeployment. Our military should not be asked to try to control a civil war, a sectarian civil war. We have heard all

the components of all the factions and all the dynamics that are going on in Iraq. Just think about our troops sitting in the middle of that and doing everything they are asked to do. We know from the report that Representative SHEA-PORTER referenced, and we know from the GAO reports. They confirm that our strategy is not working and that this conflict begs for a political solution, not a military one; though the United States can play a constructive role, and we will, and we have done so by providing, through high cost and blood and money, an opportunity to embrace a different way to the Iraqi people. We also know the toll that that country has, along the way, encountered.

Seventy-eight percent of Americans say they believe that the U.S. should withdraw some or all troops from Iraq. Sixty percent of Americans say the U.S. should set a timetable to withdraw our forces from Iraq and should ''stick to that timetable regardless of what is going on in Iraq.'' That is not because we don't care. That is because we are looking at the evidence, and we are trying to make the responsible decision for our troops, for the safety of this country and for domestic policy.

At this point, I would like to turn it over to Representative SHEA-PORTER, and we will be wrapping up here in a few moments.

Ms. SHEA-PORTER. I would also like to point out that this really is a national security issue for the United States of America. General Peter Pace was asked if he was comfortable with the ability of our Nation to respond to an emerging world threat. He paused and he said, ''No, I am not comfortable.''

We have our troops bogged down in Iraq. We do have enemies around the world, no question about it, but our military is strained. We know that the troops could not stay at this pace past March anyway, so it is natural that the President would call to bring back some of the troops in March. It is not really progress. It is just acknowledging that we have to have them back. But here is the issue: If you know there is a burglar in your neighborhood, the first thing you do is you lock your own door. We didn't do that. We went to Iraq instead of locking our own door. We didn't even pass the 9/11 recommendations. The 110th Congress had to take care of that business. So, finally, we are going to be inspecting cargo from airplanes, and we are going to be inspecting cargo that comes from overseas, and we are going to inspect 100 percent of it after a period of time. That should have been done immediately. We should have beefed up homeland security, locked our doors, so to speak, and then worked with other nations to catch terrorists. They were ready.

On 9/12/01, we had the world's sympathy and empathy. They were ready to work with us to catch these horrible terrorists. Instead, we went to Iraq, and now our brave troops are bogged down there. The Iraqis have suffered enough. It is time to bring them home responsibly and to start looking at building up our troop strength again so that we can respond to anyplace around the world that we might need to be.

Ms. SUTTON. Well said, Representative SHEA-PORTER.

Mr. Speaker, we are going to close and yield back the balance of our time.

REPUBLICAN FRESHMEN THIRD QUARTERLY REPORT TO THE 110TH CONGRESS

The SPEAKER pro tempore. Under the Speaker's announced policy of January 18, 2007, the gentleman from California (Mr. MCCARTHY) is recognized for 60 minutes as the designee of the minority leader.

Mr. MCCARTHY of California. Mr. Speaker, tonight we are having our third quarterly report to the 110th Congress. This is a quarterly report for the newly elected republican freshmen. We came here to solve problems. We came here to find partnerships. We came here to really, what we listened about during the campaign, to make America better. Tonight, I have a few freshmen joining with me.

The idea tonight is about accountability. What has gone on here in Congress? I think every time we do this quarterly report, I go and I check the Web sites. Again, today is a new record. Congress has the lowest approval rating, at 11 percent, that it has in the history of its taking a poll; lower than in the years of Watergate, lower than during the years when we were rationing and being held hostage in Iran, lower than the time of 1994 when the last time the parties switched powers here. Tonight is the night we talk about what has gone on, the accountability of what has happened here, and what has taken place.

To start us out tonight is a congresswoman from Minnesota, from St. Cloud, MICHELE BACHMANN. I yield to Mrs. BACHMANN.

Mrs. BACHMANN. Mr. Speaker, I thank my colleague from the great State of California, Congressman MCCARTHY. What a wonderful leadership role he is playing with our freshmen class.

It is true, Mr. Speaker, we are so grateful, as freshmen Members, to be here with new ideas and a new perspective. Part of that perspective is a positive outlook on life and a positive outlook on our country. One thing about Americans, Mr. Speaker, is we tend to be happy people, go-getter people, people that have ideas, innovation. We are entrepreneurs. We always look over the next hill. We always look for the next goal. We are forward-looking people.

One thing that I have been a little dismayed about in my time here in the Congress is I have heard so much negativity on the floor. As a matter of fact, in the previous Special Order, I was amazed at the level of negativity that I heard. That is not representative of the American people. It certainly is not representative of the people of the Sixth District of the State of Minnesota. They are positive people that are looking, as we Republican freshmen are looking, at new ideas, at fresh perspectives.

I was so intrigued this weekend when I was home in my district, I had the chance to read the Sunday paper. I found an article in that paper that talked about the incredible progress we have made in recent years. So much of that has to do, Mr. Speaker, with a lot of the very good decisions that were made in the previous Congresses, particularly, Mr. Speaker, the tax cuts that were passed in 2001, 2003. I say that because I am a Federal tax litigation attorney. I hate high taxation. If you speak with most Americans, they also detest high levels of taxation. One thing that the Congress did so well was to reduce that level in 2001 and in 2003. The one thing we don't want to see happen is to have the country take a dramatic turn now under the Democrat controlled House of Representatives and embrace tax increases. This really concerns us because what we have seen so far is the Democrats are now embracing what, you know, the argument is, will it be the largest or the second largest tax increase in American history? Whatever, it is a very large tax increase. But what the other formula for success has brought about, Mr. Speaker, is prosperity.

□ 1730

Prosperity not just for those who are the high income earners, not even just the middle income earners. We have seen tremendous levels of prosperity, even for those who we would consider the poor among us, who government considers the poor among us, and if there is anyone who deserves help up, a hand up, it is the poorest among us.

In this article I read this weekend, it is really a scorecard of sorts on the Republicans and the great tax cuts that they put through this Congress, and it is very good news.

If you dig into the numbers, as this author writes, his name is Jason Lewis, he is a writer from the Twin Cities, and I want to quote from this article, he writes, ''We now have a record number of Americans with health insurance.''

I will tell you what. You would never know that, listening to people speak on the floor of this House. You would think everyone is destitute and no one has health insurance. We are at an all-time high in this country with the number of people that have health insurance.

The doom-and-gloom focus says that most of those people who do not have health insurance currently live in households with incomes that are in excess of $50,000 a year. So even the people who don't have health insurance in the United States are making over $50,000 a year. In fact, many of them

today are eligible for government healthcare programs. They have just simply decided or elected not to enroll in those programs.

The median household income, more good news is that adjusted for inflation, the median household income today has risen in 2006 to over $48,451 nationwide, and in the Twin Cities in Minnesota, median household income today is at a robust $62,223.

This is great news. We should be talking about this great news. And how did we get to this level of prosperity? It is because of the tax cuts that came in 2001 and 2003, and that great investment is now paying off.

Surprisingly, in August, the figures show the first significant drop in poverty in a decade. This is great news. Shout it from the housetop, which we are. This is the ''big House.'' We are shouting it. The official rate declined from 12.6 percent in 2005 down to 12.3 percent. That is great. We want to reduce the level of poverty in the United States.

The Federal tax cuts of 2003 gave us an economy that added $1.3 trillion in real output. We have grown more than 3 percent annually, according to Investors Business Daily.

Business spending, way up, adding 8 million new jobs to this economy. Real labor compensation per hour has rebounded, because now wages have advanced 3.9 percent from a year ago.

Those are statistics. But it really means things for American families. As a woman, as a wife, as a mother of five children, we have raised over 23 foster children, I will tell you what: When your wage goes up, that means you can afford to pay the light bill at the end of the month. You can afford to have groceries. You can take your kids and buy them the clothes that they need for school. You can pay for the field trips they have to go on. And you can pay for all the sports activities that they love to do after school.

These are real benefits, when government doesn't have that money, when normal real people have this money. That is what we want, to have all households have that money, and the poorest families are the ones that need to benefit even the most.

Mr. Speaker, even with the slight decline in job creation in August, the Nation's unemployment rate remained in record low territory of 4.6 percent. Great news. Great news for today.

Robert Rector also just came out for the Heritage Foundation, and he told us among the households considered poor in our country, of those households that we call poor, 46 percent of those households in America, almost half actually own their own home. That is something that we don't always understand, that almost half of all poor people in this country own a home. If you own a home, Mr. Speaker, that is your greatest down payment on the next generation and on wealth creation.

Most people that are considered poor by our government own a car. In fact, of people considered poor, 31 percent of poor households own two or more cars. That is great, and we want to keep prosperity going for the poor.

Seventy-eight percent of those who are considered poor by the government have a DVD player or have a VCR player. In fact, 62 percent have cable or satellite TV. One-third of poor households have both cell phones and land line phones. And a stunning 80 percent have air conditioning. This is really good news, significant, because as recently as 1970, and I remember this, only 36 percent of all American households had air conditioning. My family wasn't one of those. So I am grateful that today 80 percent of the people that even the government considers poor today have air conditioning. This is great news that we have.

In fact, the study said that 89 percent of poor families themselves, and this is very important, say that they have enough food. Boy, if there is any measure of poor, it is, are you hungry? No one wants to see one child, one older person, anyone go hungry in this country. Eight-nine percent of people who themselves are categorized as poor say that that they have enough food. Only 2 percent of that category say that they don't.

That isn't to say, Mr. Speaker, that there are not serious problems for those who live below the poverty line. Trust me. The foster children that we took into our home, they were categorized in this category. There are needs aplenty for those who are below the poverty line. We need to address those needs.

That being said, there is good news out there. Let's celebrate the fact that Census Bureau figures don't even include when they categorize people that are poor the value of non-cash benefits. So if you are poor, the government doesn't even include the fact of the amount of money you receive in food stamps. They don't include the amount you receive in housing subsidies, in Medicaid, or even the Earned Income Tax Credit. That is to say, and this again is good news, that the gap between the poor and average households is even smaller than sometimes what it is stated to be.

That being said, we are now at a juncture, Mr. Speaker, when we are looking at a turn. I know my colleagues that are also going to be speaking in the freshman class are going to be talking about this turn.

I will end on this note, because I gave a lot of great news. The negative news that we are looking at is that so far in this Congress, the Democrat majority in the House has passed their budget, and their budget included, again, the largest, or however you want to parse it, the second largest tax increase in American history. I just want to say that for the people of my district and the people for your district, they will probably have to be paying an additional $3,000 a year for every average American family, and that will negatively impact the poorest among us the most.

So we have two choices in front of us: Do we want to continue with lower taxes and prosperity, where the poorest among us have seen actually tangible benefits? Or do we want to take the route that the Democrats have proposed, and increase taxes knowingly $3,000 a year on my family, on your family, on families in our districts? I can't abide by that, especially for the low-income families in my district.

With that, I say let's do what our founders would want us to do, and that is to embrace hope, prosperity, new ideas and a fresh perspective.

Mr. Speaker, with that, I yield back to the kind gentleman from California, Congressman MCCARTHY.

Mr. MCCARTHY of California. Mr. Speaker, I thank Congresswoman BACHMANN for her talk. You can see from her enthusiasm, you can see from being a mother of 23 foster children, that she brings hope, not only to America, but to Congress. She brings a problem-solving idea, trying to find some commonsense ways actually to make change here. We are so proud to have you here.

As I said, this is the third quarterly report put on by the freshmen Republicans on accountability of what has gone on here in Congress. We want to bring it back to your house, Mr. Speaker, to let people know what has gone on on this floor.

There is a reason why America has lost faith in their Congress. The approval rating is now at 11 percent, the lowest in the history of any poll on the approval rating of what has gone on in Congress. So tonight we want to talk about what has happened here. But we want to also talk about our future and how we can make things better, how we can find common ground, how we can actually bring hope back to America and have real change.

Tonight I have the honor of introducing one of the superstars in the freshman class. He comes from the Sixth District of Illinois, Congressman PETER ROSKAM from Wheaton, Illinois. I yield to the gentleman.

Mr. ROSKAM. Mr. Speaker, I thank the gentleman.

Mr. Speaker, I really appreciate Congressman MCCARTHY's leadership this afternoon and this evening, this opportunity to have a conversation and really to reflect on what it is that we have been sent here to do. I know that I and my colleagues that join me here on the floor, Mr. Speaker, are people that came here as problem solvers. We didn't come here to fight partisan fights. We didn't come here to have sharp elbows. We didn't come here to call people names. But we came here to try to get something done.

We represent districts that are really commonsense districts, that have a high expectation of this process. I know that all of us who are on the floor today, we don't celebrate in the very low view that the American public has

of the Congress under this current leadership. We don't celebrate in that at all. In fact, we mourn that in many ways, because there has been a real lack of leadership and a lack of an opportunity.

I think whenever you have conversations about how you are doing so far, and this is our third quarterly report that the Republican freshmen are participating in, it is always in the context of looking at what the expectations were as the 2006 elections came about. What was it that people said, that the American people trusted in, that the American people believed in, that the American people cast their votes for? What was it, that rhetoric that called people forth?

I think we don't have to go very far to really look at the rhetoric from the 2006 campaign and look at the comparison to the accomplishments in 2007, and you can see why 89 percent of the American public says, ''that's not what I voted for.'' So let's kind of refresh our memories.

First off was that we were going to be a very hard-working Congress. The 109th Congress, we were told, was essentially lazy and wasn't accomplishing anything. That was the characterization of the previous Congress under the previous leadership. In fact, we were told that during the next year, Members of the House will be expected in the Capitol for votes each week by 6:30 p.m., and will finish their business by about 2 p.m. on Fridays, we were told by then Minority Whip HOYER.

Well, as it has come into fruition, here we are, it is 5:40 p.m. in Washington, D.C. There is plenty of time for us to be doing substantive work, amending bills, debating bills, considering things. We could all be in committees. And yet the House is quiet today, and here we have this time to be reflecting on what the performance has been.

I regret that. My sense is that we are here to work, and we are willing to work, and we are anxious to work. Yet the way that the majority has structured the calendar, there is simply too much time. Of the 21 weeks in session, only six have included five full days of work. That is according to the official website of the Clerk of the House of Representatives.

Or, we were told that the Members of the House would have at least 24 hours to examine a bill and a conference report text prior to floor consideration. That is what the gentlewoman from California, Ms. PELOSI, said in her publication, ''A New Direction For America.'' She also said, and it was reported in the Washington Post, that she would insist that bills be made available to the public at least 24 hours before they would be voted on by the full House. Yet the reality, Mr. Speaker, is far different than that.

You know, it is one thing to not make a big deal about something in a campaign and then follow through and you keep things the way they are. But it is an entirely different situation to create this overarching sense of expectation, to create this sort of nirvana invitation, to come to this new 110th Congress where everything is fantastic, and you are just going to love serving here.

Yet the harsh reality is this: The following bills did not enjoy that generous 24 hours notice: The following bills are H.R. 1, the very first bill of this new Congress. H.R. 1 did not enjoy a 24 hour notice period.

Now, let's think about it. Is 24 hour notice the biggest deal in the world? No, frankly, it is not. It is not the biggest deal in the world. There is a little bit of process argument to it and there is a little bit of inside baseball feel to it.

□ 1745

But the point is the current majority leadership created the expectation that 24-hour notice was going to be the standard. So here are just a few things: H.R. 1, H.R. 2, H.R. 3, H.R. 4, all of the first bills, no 24-hour notice. H. Res. 35, the intelligence oversight authority, not the ability to have 24-hour notice. H. Res. 296, H. Con. Res. 63, and on and on and on, no 24-hour notice.

Or we were told by Mrs. PELOSI in the last election cycle, she is quoted as saying, ''Rules governing floor debate must be reported before 10 p.m. for a bill to be considered the following day.'' That sounds great. But the problem, you see, is that the Democrat majority leadership hasn't followed through on that.

According to this report which was put together fairly quickly, nine bills with the twinkling of an aye haven't enjoyed that notice.

As we are moving forward and considering this, my district is sort of interested in the process, Mr. Speaker, but they are really interested in the substance of this Congress. This is a group that is now in the leadership and now in the majority that made very clear promises about what, fiscal discipline and fiscal responsibility. And those are things that deeply resonate in the district I represent.

This is what Mrs. PELOSI said. She said, ''Democrats are committed to ending years of irresponsible budget policies that have produced historic benefits.''

Additionally, she said, ''We will work to lead the House of Representatives with a commitment to integrity, to civility, and to fiscal responsibility.'' That sounds fantastic.

You go door to door in the Sixth Congressional District in Illinois, you go door to door in Mrs. BACHMANN's district, you go door to door in Mr. MCCARTHY's district in California, and you say I am going to stand for fiscal responsibility, and they say, hip hip hurray, go to Congress. You go do the right thing.

But where the breakdown has happened or the disconnect has happened is when people say, hey, I voted for fiscal responsibility. I voted for fiscal discipline. That's how I cast my vote last November. And now they come into the third quarter of this year and all of a sudden they realize that is not happening. That is not even close to happening. Oh, they are spending money like there is no tomorrow. That is how this majority has approached the budget situation.

Do you remember the conversation we had on the earmark process on this House floor, Mr. Speaker? Earmarks are those abilities to sort of put a little Post-it note in an appropriations bill, and the note says this money is going to be spent on this particular program in this particular way.

There are some people who say all earmarks are bad. I don't necessarily think that is true, but I think all earmarks should be transparent. People should have the ability to look at the Federal budget, people should have the ability to look at the appropriations bills and look at the work of Congress and say, who is behind that spending item, what is motivating that person, and where is it going.

Well, what we were told is that these earmarks would be transparent. In fact, we were told throughout the course of the 2006 campaign what the Democratic leadership wanted to do was completely transcend the earmark process and open it up to sunshine and goodness and light. But the reality was much different than that.

The reality was it was the Republican minority in this Chamber that had to fight tooth and nail on this floor to drive the appropriations process open so that earmarks were transparent because the way it was originally set up was that we were told that all we could do was simply write a letter if we had an objection to an earmark to the chairman of the Appropriations Committee. That is simply not good enough.

So as we are reflecting today and looking about at what is it, how is it that an institution that is to be celebrated, an institution that is to be admired, an institution that is to be respected, is now down at an approval rating at an all-time low? I regret that. I am sad about that. I don't celebrate in that.

I think what has happened is the American people have come to the conclusion that the rhetoric of the Democrat majority, the rhetoric of the leadership of the Democratic Party, the rhetoric of the last campaign simply doesn't match with the reality of what they are seeing in Congress. And so the promise to make this the most ethical group in history hasn't come to fruition. The promise to be fiscally disciplined has not come to fruition. The promise to make this process open and accessible to all hasn't come to fruition.

I think that, Mr. Speaker, in large part is why we are now at this historic low of 11 percent. I think we can do better. I think there are some of us

who are on the floor this afternoon and evening who want to be problem solvers. There are some of us who want to get things done. There are some of us who understand that living within our means means making fundamental choices and decisions.

We were elected as leaders, and yet sometimes there is a temptation, which I sense on the majority side that they simply want to kick the can down the lane and have another Congress make the tough decisions.

Mr. Speaker, I was sent here to make tough choices and I stand ready with these good colleagues. We are here calling balls and strikes. We don't come in as harsh critics of everything. We are not simply here about donkeys and elephants necessarily, but we are here talking about those things that ought to bring us together as Americans, and that is the ability to work together towards solutions, to make the tough choices now and not defer them to future generations.

Mr. MCCARTHY of California. Mr. Speaker, I thank Congressman PETER ROSKAM. He makes a good point that you may campaign as a Republican or a Democrat, but when you come here, you should come to the issues as Americans. That is how we come to you tonight, looking for common ground, and the place where we can actually solve problems. That is what we campaigned on and made a promise to do, and that is why we are before you.

Just as when you are back home sitting at your table with your children, and I have mine, Connor, 13, and Megan, 11. I look for their report cards. I look at their grades. Tonight we are going to talk about Congress's grades.

The next speaker we have tonight is an individual from Ohio. He was a State senator, kind of a star there as well as on match, a wrestler, an NCAA champion. And currently, he is serving on Judiciary, Oversight and Government Reform, and Small Business. He is also looking out after us when it comes to the budget.

Mr. JORDAN of Ohio. Let me thank the gentleman from California for putting this together. I appreciate the chance to be with you and some of my colleagues from the freshman class.

I particularly want to reference the tone that the gentlewoman from Minnesota brought to the discussion this evening. She talked about the optimistic can-do spirit that has always been a part of this country and that is alive and well today. Frankly, we are going to need that spirit when we confront the challenges that we face.

I call it the David attitude. You may remember the old story from Scripture. When the Israelites were camped against the Philistines, and every day the Philistine giant would walk out and issue the challenge. He would ask: Who will fight Goliath?

The Israelites' response was: He is so big, we can never defeat him. But David's response was: He is so big, I can't miss.

That is the attitude we need to confront the challenges we face. You think about the challenges that America faces today, unprecedented in our Nation's history.

First, we have the terrorist threat as real and serious as it gets. We have this debate in our culture over whose set of values are going to win. There is a core set of principles, a traditional set of American values that made this Nation special. We should not be afraid to defend and protect and promote those principles and values.

But the challenge I want to focus on tonight is fiscal discipline. This is so, so important. Many of us have been back home over the last 6 weeks talking to all kinds of folks across our congressional districts. Many times what I do when I am speaking in front of a group, I say, you all may find this a surprise, but the Federal Government spends a lot of money. Everyone starts to laugh. And I say, they spend a heck of a lot of money.

The Federal Government spends $23,000 per household per year. We have an $8 trillion national debt. We have spending that is out of control. If we don't get a handle on that, what we are going to do to future generations is going to be difficult and it is going to make it tough for us as a Nation to continue to be number one economically.

I like to remind folks that the way the world works today, the economic superpower is also the leader in the military area. The economic superpower is the military superpower. Right now that is the United States of America, and I believe the world is safer because of that fact. We want America to lead diplomatically, we want America to lead militarily, and we want America to lead economically. It is important we do that. When America leads, the world is a safer and better place. And we want to make sure that continues.

In order for that to continue, we have to get spending under control. Over the course of the budget process, the budget that the majority party brought forward would in essence raise taxes over the next several years over $200 billion. When they look at scaling back the good tax cuts that were put in place back in 2001 and 2003, that have helped our economy respond to some of the hardships we faced after the 9/11 attacks and the recession that followed, we need to make sure that we get spending under control.

We always hear about tax-and-spend elected officials, tax-and-spend politicians. In fact, I would argue it is the opposite. It is spend and tax. Spending always drives the equation. We have to get spending under control.

In the appropriations process that we went through this summer, 12 different spending bills that finance the government over the course of the fiscal year, of those 12 bills, nine are nondefense. To those nine bills we offered a series of amendments that would have held spending at last year's level. It wouldn't have been a cut. It would have simply said to the government, the government that already spends $23,000 per household, it would have simply said: We want the government to spend what we spent last year. After all, all kinds of families have to do that, and all kinds of taxpayers have to do that, and all kinds of businesses have to do it from time to time. Why can't the Federal Government do the same thing?

Yet we heard from the majority party we can't do that. If we would simply spend what we spent last year, the sky would fall. The world would end. We have to have more of the taxpayers' money. That is the argument we heard. But it was not a cut; it was simply level spending. If we would have been able to do that, we would have saved taxpayers $20 billion and helped to begin to put us on a path to deal with the financial problems that will come if we continue to deficit spend.

Don't take my word for it. A former governor on the Federal Reserve Board, Dr. Edward Gramlich, said this: ''Budget deficits lead to less economic growth and a lower level of economic activity than would otherwise be the case.''

Mr. Walker, the comptroller general said, ''Today, we are failing in one of our most important stewardship duties: our duty to pass on a country better positioned to deal with the challenges of the future than the one we were given.''

One of our fundamental challenges as people elected to public office is to make sure that the next generation has it better than we did. If you think about what has really allowed America to grow and prosper, we are the greatest country in the world for all kinds of reasons and all kinds of policies that we have, but in the end it is that parents have been willing to sacrifice so that their kids can have life a little better than they did. That kind of philosophy should be present in how we run the United States Congress and how we run government and how we spend taxpayer dollars.

Unfortunately, those amendments weren't passed and we were not able to save over $20 billion to help to begin to put us on a path towards greater fiscal responsibility. It is important that we do that, and it is important that we do it for the future of Americans. But we are going to get there.

The gentlewoman from Minnesota is right; Americans always figure out a way to address the obstacles and hurdles that are in front of us, and we will figure out a way to do this. We just need to keep talking about it and stay diligent. If we do that, we will put our country on the path that it needs to be fiscally so we continue to be that leader economically, militarily and diplomatically.

I appreciate what the gentleman from California is doing in helping to lead our freshman class and thank him for a chance to be a part of this hour this evening.

□ 1800

I want to thank the gentleman from Ohio because he is right. Many people talk about the tax and spend, but really it is the spending that drives it. Just from last year, with the bills that were passed on this floor with the largest tax increase in American history, they increased spending by 9 percent. A lot of people ask out there: What was the spending on? How did you go about doing it? I think that is what we are going to talk about tonight.

Before I get to our next speaker, I just want to show a couple of little slides here about where we are going. First, you see the promise that was made, that the gentleman from Illinois talked about, what Speaker PELOSI had said: ''Democrats are ready to lead, prepared to govern, and determined to make you proud.''

Today, we sit at an 11 percent approval rating of this new majority. That is the lowest in the history that they have ever taken the poll. Lower than in the years of Watergate. Lower than when we had to ration gasoline during the years of President Jimmy Carter. Lower than in 1994 when the public decided after 40 years they wanted to change the majority here and put the Republicans in charge. It is now at the lowest level.

Why? And why is that spending taking place? I want to tell you an example, and I actually saw this on the news the other day, and I credit the news, Mr. Speaker, and CBS doing a story on this. What are we spending our money on? You sit around that table and you decide where you put your money away and where you go to save. Let me tell you a little story. It happened right here on this floor.

I was sitting down here and I was watching, and one of those spending bills, the Health and Human Services, there was $2 million put in. You say was it put in for education? Was it put in to make America greater? It was put in by a Member, Mr. Speaker, to name a library after himself. Two million dollars was spent. What did it say within here that it needed to be? You needed $2 million for the new Rangel Conference Center, a well-furnished office for CHARLES RANGEL and the Charles Rangel Library. In the brochure, when you look at this library for a college that the library is not even there yet, it will say it will be as nice as President Clinton and as nice as President Jimmy Carter. Well, those libraries were funded by private funds. Those people were Presidents.

Now, what do you say? Maybe this is something that every chairman of Ways and Means would do. It just so happens the Member that served and represented Kern County, where I represent, was chairman of Ways and Means just a year ago. What did he do with his papers? He didn't name a library after himself. He took his papers to the junior college, Bakersfield Junior College, and gave them to them, where the kids can go and look and read.

Well, you know what happened? Just like Mr. JORDAN had said, there were many amendments on this floor, many amendments by this freshman Republican class that said we want to get spending under control. There was an amendment by a Congressman from California, JOHN CAMPBELL, Mr. Speaker, that wanted to take that $2 million out. He thought that wasn't the best way to go about it. Much as the Congressman from Illinois said, earmarks. This is what an earmark is all about.

Well, just behold, the Congressman that had put this in, Mr. Speaker, Mr. RANGEL, came to this floor. He said he was proud of this. One of the Congressmen asked him: ''Well, if it's going to name it after yourself, should we name one after ourselves?'' He said: ''No, they don't deserve it. They haven't been here long enough.''

Mr. Speaker, this is the monument to me, but it is the monument to me paid by taxpayers. It is a monument to me, where not even the college asked to name it after him. He asked to name it after himself.

I am proud to tell you that all 13 freshmen Republicans voted for the amendment to strike out this earmark, to stop this type of activity. This is why we ran, this is what we said we would do, and this is not what the Democrats in the majority party said they would do when they were in control.

This is what has got to stop. This is why spending is 9.3 percent higher, and it's paid by taxpayers' money. I don't think the Members across this country wanted this to take place, I don't believe this person was the President of the United States, and I think individuals that are chairmen of Ways and Means ought to look for the path of what Congressman Bill Thomas did when he was chairman of Ways and Means, he gave his papers to a junior college. He didn't put $2 millions in to have nice furniture and an office and a librarian, to be as nice as the presidential libraries are.

Having said that, Mr. Speaker, we have some more Members with us tonight. We have an individual from Tennessee, the First District of Tennessee. He served in the legislature back there. You may recognize him. He is on the floor quite often talking about bringing America back, finding solutions here.

I yield to Congressman DAVID DAVIS.

Mr. DAVID DAVIS of Tennessee. I thank my friend from California. Thank you for your leadership tonight. Thank you for pointing out some of our spending and taxing waste. I would like to thank my colleagues that have spoken before me tonight.

I have been absolutely pleased with the group of freshmen Republicans that I came in with, a group of men and women that are very honorable, willing to work hard and do the right things. Thank you so much for serving with me in Washington.

I look back at one of my favorite Presidents, a President that was enjoyed by Republicans, conservative Democrats, independents, and that President was Ronald Reagan. Ronald Reagan once said, ''We don't have a trillion dollar debt because we haven't taxed enough. We have a trillion dollar debt because we spend too much.'' It goes right back to what we have been saying, spending then taxing.

There are many people sitting around their kitchen tables around America tonight trying to decide just how they are going to put their budget together, how they are going to make their car payment, how they are going to send Junior to school, Sissy to school, how they are going to pay for their health insurance. Those families are having to make hard decisions. The Government, this Congress could learn from those Americans sitting around kitchen tables.

I did come from the mountains of east Tennessee. Those people back in the mountains of east Tennessee have a lot of common sense. They have enough common sense to know that you can't spend more than you take in, and you can't tax people to death and expect success. That is exactly what this Congress is doing.

According to the Congressional Research Service, the President's program of comprehensive tax reforms, President Bush's tax reforms and the congressional Republicans when they were in charge, those tax reliefs were well-timed to respond to a weak economy. My colleagues have spoken about it. We had terrorist attacks. We have had natural disasters.

That tax relief enacted in 2001 granted immediate tax rebates, reduced marginal tax rates, and lowered the marriage tax penalty. It actually allowed Americans to keep more of their money in their pocket so moms and dads can take care of their families.

My wife and I have two children. We fundamentally believe that we can take care of our children better than some bureaucrat in Washington, D.C. I think it's just common sense. I think there are many people across America, it doesn't matter what party you're part of, it doesn't matter if you're Republican, Democrat or independent, I have just got to feel that you believe you can spend your money better than Washington can as well.

Then, to go on, the tax relief of 2003 accelerated the much-anticipated and successful tax cuts of 2001. Those tax cuts of 2001 and 2003 actually strengthened our economy. The Republican tax relief has seen nearly 4 straight years of economic growth, while adding 7.5 million new jobs into our economy. That is the success that MICHELE BACHMANN spoke about.

Things are going very well, and I am glad to see that. The Congressional Budget Office confirmed that the tax cuts of 2003 helped boost Federal revenues by 68 percent. Again, it's not partisan. It works every time. When Democrat John F. Kennedy cut taxes, the tax increase into the Federal Government increased. The economy got

stronger. It happened when Reagan did it, and it happened when Bush did it. It is not partisan, it is just fact.

We must make the successful tax cuts of 2001 and 2003 permanent. If they are not made permanent, which I am convinced that this new hold-on-to-your-wallet Congress is not interested in doing, here's what will happen: 84 million women will see their taxes increase by $1,970. If you're female and you're listening to me, this Congress is going to raise your taxes by $1,970. Forty-eight million married couples will see their taxes increase by $2,726. Forty-two million families with children would see their tax bill go up $2,084. Twenty-six million small business owners would see a devastating $3,637 tax increase, the very small businesses that are creating the jobs in the economy. Five million low-income individuals and couples will no longer be exempt from individual income taxes.

We must make the 2001 and 2003 tax cuts permanent. Unfortunately, I am convinced that we will not see those tax cuts made permanent under the spending I see going on on the floor of this House. When we see those tax cuts start to be repealed, we are going to start to see the economic growth actually come to an end.

Washington Democrats have passed a fiscal blueprint that raises taxes by almost $400 billion on millions of Americans in one fell swoop. As part of their ill-gotten budget, taxpayers in Tennessee will not be allowed to deduct their sales tax from their Federal income tax. Taxes on small businesses, as I said earlier, will go up. The child tax credit will decrease from $1,000 to $500. The marriage penalty is coming back.

Residents of the First Congressional District in Tennessee's average tax expense is going up over $2,000. The definition of a small business will decrease from $400,000 to $200,000. Dividends will no longer be taxed at the personal gains rate, thereby increasing the double taxation on dividends by as much as 62 percent.

People all across America voted for change, but they are not getting the change that they wanted in the last election. Over the last quarter there were a couple of bills we have talked about and passed on this floor without my vote, and one of them was the energy bill. The energy bill that we passed had plenty of taxes, very little energy.

The Democrat majority in the energy bill actually decided to tax American oil producers at the level of 16 billion extra dollars. American oil producers. If we take the ability for American oil producers to produce oil, it makes us more dependent on foreign oil, on countries that hate us and hate our freedoms. I think that is the wrong direction for America. I don't think that is the change that the American people voted for.

Then we had the SCHIP bill. It sounds good, giving poor children health care. We all certainly want to do that. I am for continuing the program at its current level. But at the level that passed on this floor, the Heritage Institute said it will take 22 million new smokers to pay for the bill. Now, is there anyone in America that wants to see 22 million new children have to take up the habit of smoking to pay for a health care bill?

In addition to that, they decided that wouldn't be enough to pay for it so they actually added a tax on your health insurance premiums. So if you buy your own health insurance, your taxes will go up.

We have a choice between a bigger economy or bigger government. The majority party has made a choice. They are for bigger government. Congress has an approval rating down now to 11 percent, and I can certainly understand why we have such a low rating. We need to hold the line on spending, reduce earmarks, pass a line-item veto and crack down on worthless pork-barrel projects and be good stewards of the taxpayer.

Remember, Ronald Reagan once said: ''We don't have a trillion dollar debt because we haven't taxed enough. We have a trillion dollar debt because we spend too much.'' I think we need to start running Congress like the American family has to run their household budget.

Mr. MCCARTHY of California. I want to thank the Congressman from Tennessee, Congressman DAVID DAVIS. I appreciate your talk directed to the people back home, telling them we should run Congress much like you run your house. It is not being done today.

As we heard earlier from the Congressman from Ohio about the spending, we heard from Congresswoman MICHELE BACHMANN from Minnesota, we have found that we are not talking about hope here, we are talking about the largest tax increase in American history, because that is what has gone on on this floor, and we want to make a real change about it.

I now have another freshman who is joining us. He comes from Colorado, Colorado Springs, the home of the Air Force Academy, Congressman DOUG LAMBORN.

Mr. LAMBORN. I thank the gentleman from California.

It's a pleasure to be here with my fellow Republican colleagues as we talk about fiscal responsibility. I rise today with new poll numbers in hand regarding the performance in Congress under the Democratic majority. According to a Reuter's/Zobgy poll released earlier today, a measly 11 percent of Americans approve of the job Congress is doing. The American public is disappointed with their government, and understandably so.

When the Democrats took charge in January, they promised to usher in an age of fiscal responsibility. Instead, they propose to hit 115 million American families with new tax increases totaling $392.5 billion. That is almost $400 billion.

In addition, the Democratic Congress has also fallen short on their promise to enact serious earmark reform. As a result, wasteful earmark spending continues to be a problem. This is evident by Democrat Congressman CHARLIE RANGEL's $2 million earmark to pay for a building to be named in his honor. You heard some about that earlier. Ninety-seven percent of Democrats, who only a year ago told the American people they would restore responsibility to government, voted in favor of this self-glorifying measure at the taxpayers' expense.

In a time, Mr. Speaker, when the Federal Government faces an $8.8 trillion national debt, this Congress must demonstrate to the American people that we can be fiscally disciplined and that we can spend their hard-earned tax dollars responsibly.

I am proud to say that Republicans have been leading the fight for this in the 110th Congress. Increasing the size of the budget and allowing earmarks to go unchecked will not reduce the deficit. I look forward to continuing my work on this effort with my Republican colleagues as we attempt to restore sanity upon the out-of-control spending practices of the Democratic majority.

□ 1815

At this point, Mr. Speaker, I would yield back to the gentleman from California.

Mr. MCCARTHY of California. I thank the gentleman from Colorado, and I appreciate his opportunity to come down and talk with us.

As I said earlier, as we talked about the accountability of what has gone on on this floor and we said, why has spending increased by 9.3 percent from last year? And we talked about the majority here and how they have had the ''Monument to Me,'' where they put $2 million in to name a library after themselves.

When you talk about earmarks, when you talk about transparency, this is what we are talking about. We can find ways that we can eliminate waste, fraud and abuse. That is what the American people want to have happen here. I don't believe the taxpayers of America think Members of Congress deserve $2 million libraries with well-furnished offices and a library for your papers and memorabilia, that taxpayers should be spending their money on that. I think we should be spending their money in the classroom teaching our kids to read and write English. That is what we should be spending our money on.

But I will tell you, we have another Member, a brand new Member of the freshman class. Unfortunately, there was a death after the election by Congressman Charlie Norwood in Georgia, and that special election has taken place and we have a new Member to join with us tonight. He actually has some late-breaking news that he wants to share with us, so I would like to introduce and yield what time he desires

to Congressman PAUL BROUN, representing Augusta and Athens.

Mr. BROUN of Georgia. I would like to thank Congressman MCCARTHY for yielding me time to speak on the floor this afternoon.

This afternoon, it was reported that Iranian President Mahmoud Ahmadinejad sought permission from the City of New York and the United States Secret Service to visit Ground Zero, the site of the September 11 attacks. This is an outrage, that this person would request to go to the place that he and his terrorist brethren have caused such destruction in this country.

President Ahmadinejad is coming to the United Nations as the representative of a country, Iran, that the State Department has declared the ''world's most active state sponsor of terrorism.'' His presence at Ground Zero would represent a slap in the face not only to those who were lost in the attacks on September 11, 2001, and to their families, but to all Americans.

Make no mistake about it, Iran is a rogue nation that views America and the Americans as their enemy. General Petraeus and Ambassador Crocker just spent a significant amount of their time recently here on the Hill detailing the Iranian efforts to come against our troops and kill our boys and ladies in Iraq. To allow Ahmadinejad to abuse his status as a diplomat to visit this site would send a signal that we fail to take the threat that he and his country bring to this Nation and to our people in a serious manner.

What kind of man is Ahmadinejad? Please let me read you some of the public policy positions as compiled by the Jerusalem Post.

He denies the Holocaust. ''We ask the West to remove what they created 60 years ago; and if they do not listen to our recommendations, then the Palestinian nation and other nations will eventually do this for them.''

''The real Holocaust is what is happening in Palestine, where the Zionists avail themselves of the fairy tale of Holocaust as blackmail and justification for killing children and women and making innocent people homeless.''

''The West claims that more than 6 million Jews were killed in World War II, and to compensate for that they established and support Israel. If it is true that the Jews were killed in Europe, why should Israel be established in the East, in Palestine?''

''If you have burned the Jews, why don't you give a piece of Europe, the United States, Canada, or Alaska to Israel? My question is, if you have committed this huge crime, why should the innocent nation of Palestine pay for this crime?''

His quotes about threats against Israel: ''Anybody who recognizes Israel will burn in the fire of the Islamic nation's fury.''

''Remove Israel before it is too late, and save yourself from the fury of regional nations.''

''The skirmishes in the occupied land are part of a war of destiny. The outcome of hundreds of years of war will be defined in Palestinian land. As the Imam said, Israel must be wiped off the map.''

''If the West does not support Israel, this regime will be toppled. As it has lost its raison d'etre, Israel will be annihilated.''

''Israel is a tyrannical regime that will one day be destroyed.''

''Israel is a rotten, dried tree that will be annihilated in one storm.''

Late this afternoon, this very afternoon, the New York Police Department indicated that they would not issue a permit to Ahmadinejad. I hope they stand firm on this decision, and I applaud that decision. However, we should go one step further. This despotic, Holocaust denying madman should not be allowed in this country. I call upon the State Department and the President to do the right thing; refuse Ahmadinejad an entry visa.

Mr. MCCARTHY of California. I thank the Congressman from Georgia bringing forward exactly what is going on right now in America.

I would like to, as we have a few moments left, turn back to Congressman PETER ROSKAM from Illinois and yield him the time that he desires.

Mr. ROSKAM. I thank the gentleman for yielding.

I think one of the things that is upon us is this time, Mr. Speaker, that we are in as a country right now and we are really in, essentially, a time of choosing. And there are great weighty issues that are before us as a Nation. There are great challenges that we face today, and yet this Congress is not taking up those challenges. Let me give you an example.

Today, we have the free market. That is something to be celebrated and something to be heralded and something to be defended, because the free market has brought about more prosperity for this country, for more people than the world has ever known. Yet, in many ways, the free market is under attack. And so this Congress, if it chose to, could stand up and defend the free market and celebrate the free market and say we are going to stand by the free market. But, no, actually there has been an attitude that has crept into this Congress that says, no, no, no, the free market is something that brings people down. The free market is something that is to bring suspicion on people and ought not to be celebrated.

Or, that other thing that we are dealing with, and that is that notion of energy independence. This Congress, if it chose to, could come together in a bipartisan way and create the environment where we strive towards energy independence, where we are not dependent on a complicated and difficult part of the world, Mr. Speaker, and that is the Middle East; where we are not dependent on them for our economic vitality and, ironically, for our national security; where we are not funding in many ways indirectly the very people that do us harm. This is the time of choosing.

I think that the reason that we are seeing that this leadership is at an 11 percent figure, and that is almost hard to do if you think about it, to have almost 9 out of 10 people disapproving of you, is because they have squandered this opportunity to deal seriously with these issues.

Mr. MCCARTHY of California. I thank the Congressman from Illinois, Mr. PETER ROSKAM, and all those who have joined with us tonight.

Mr. BILIRAKIS. Mr. Speaker, before I begin, some of you may have noticed that I have a different haircut. This past August, I kept a promise to my local American Cancer Society chapter that I would shave my head if they met their fundraising goal.

My promise was grounded in an effort to bring greater awareness to the American Cancer Society's work on finding a cure for a disease that some estimates show will claim more than 559,000 lives in 2007.

The statistics on cancer are mind numbing. Cancer strikes one out of two men and one out of three women, killing 1,500 people every day.

Having been at the front lines of cancer research and services for more than half a century, the American Cancer Society remains a pillar of hope for millions of Americans facing this dreadful disease.

I encourage my colleagues to get out there and support the work of organizations like the American Cancer Society. The war against cancer is a war we must, and can win—but only together.

Well, it has been more than 9 months since the 110th Congress convened under the leadership of Democrats who promised the American people many things, but have since failed to deliver on many of their commitments. This is most evident in recent approval ratings of this Democrat-run Congress, which have reached historic lows.

These numbers say everything about the failed promises of this majority. During the 2006 campaign, the Democrats pledged to rein in spending, yet their budget proposal contains more than $217 billion in tax increases, representing the second largest tax increase in American history, and proposes spending $23 billion above the amount proposed in the President's budget blueprint.

This is not the kind of reform promised by the new Democrat majority; rather, it is very reminiscent of the old Democrat majority that took more money out of the American taxpayers' wallets, while creating new wasteful spending and sprawling government programs.

Now, if the numbers are too much to bear, perhaps we can look at a particular issue of great concern to my constituents, my fellow Floridians, and residents of disaster-prone regions throughout the United States. That is the outrageous cost of homeowners' insurance.

Our national economy, and the quality of life for many Americans is severely burdened by the fact that disaster-prone areas, like Florida, continue to suffer from an insurance market that has overblown its rates and refused to take the necessary risk to ensure that every homeowner has access to affordable, quality homeowners' insurance.

Earlier this week, my Democrat colleagues took to the House floor to proclaim their outrage over the troubles homeowners are currently facing throughout the United States as a result of the tanking subprime mortgage market.

I want you to know that the concern of this body should focus on these same homeowners, in addition to the millions of homeowners who can pay their mortgage, yet are not adequately insured. This disparity is a tragedy of equal or greater measure.

You see, faced with increasingly expensive and limited insurance options, Florida embodies the kinds of problems plaguing homeowners in high-risk areas across the country.

Owning a home is fundamental to the ''American Dream.'' It should not be an insurmountable burden. Sadly though, such a possibility is slowly eroding under unbelievably high homeowners' insurance.

As we speak this week about improving the opportunities for existing and future homeowners, we must not forget the next catastrophe is just around the corner for millions of American homeowners. This catastrophe is not limited to the prospect of home foreclosures, but also hurricanes, flooding and other disasters both man-made and natural.

If the American homeowner cannot adequately protect themselves from these dangers, then they are just as vulnerable to losing their homes as those who are facing the subprime credit debacle.

I recently introduced legislation that would allow Gulf Coast States to pool their resources and jointly coordinate responses and preparation for major disasters. The Gulf Coast All-Hazard Readiness Act would allow the Gulf Coast States to form an interstate compact to mitigate, respond to and recover from major natural disasters.

Additionally, I have cosigned important legislation that would remedy the skyrocketing cost of homeowners' insurance in disaster-prone regions of the country. These bills, H.R. 91 and H.R. 330, will go a long way to addressing a problem that is only getting worse.

I implore this body to act, and for this Democrat-led majority to make good on their promise to protect American families. They can start by allowing a vote on legislation that will help families adequately protect their homes from future and almost certain disasters.

GENERAL LEAVE

Mr. MCCARTHY of California. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous materials therein.

The SPEAKER pro tempore (Mr. WALZ of Minnesota). Is there objection to the request of the gentleman from California?

There was no objection.

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF H.R. 2881, FAA REAUTHORIZATION ACT OF 2007

Ms. SUTTON (during the Special Order of Mr. MCCARTHY of California), from the Committee on Rules, submitted a privileged report (Rept. No. 110–335) on the resolution (H. Res. 664) providing for consideration of the bill (H.R. 2881) to amend title 49, United States Code, to authorize appropriations for the Federal Aviation Administration for fiscal years 2008 through 2011, to improve aviation safety and capacity, to provide stable funding for the national aviation system, and for other purposes, which was referred to the House Calendar and ordered to be printed.

IMMIGRATION

The SPEAKER pro tempore. Under the Speaker's announced policy of January 18, 2007, the gentleman from Iowa (Mr. KING) is recognized for 60 minutes.

Mr. KING of Iowa. Mr. Speaker, it is a privilege to be recognized to speak here on the floor of the United States Congress and have the opportunity to address you—while I understand that there are—many of our Members overhear this conversation that we are having and so do the American people. That is the important part about this; it is the people's House and the people need to be heard.

And I would take us back to, Mr. Speaker, the people were heard. They were heard on the immigration issue. They were heard on that issue twice in this year, in this legislative year, Mr. Speaker. And that is, even though we had a great number of immigration hearings before the Immigration Subcommittee here in the House of Representatives, and where I am ranking member on the Immigration Subcommittee we listened to dozens and dozens of witnesses that testified across the breadth of this issue of immigration that has been on the front of the minds of the American people. It has been in the front of our minds for the last about 2 years, and it becomes part of debate in every conversation that has to do with American policy.

Certainly, being a Member of Congress from the State of Iowa where we are the first in the Nation caucus, we have a number of presidential candidates, both Democrats and Republicans, that are in that State much of the time. It is a rare night that the shades aren't closed and there isn't at least one presidential candidate that is spending the night in Iowa after having spent the day and will spend the next day there. In fact, just at the Iowa State game last Saturday, I ran into two presidential candidates just random, not planned, just by the fact of the circumstances. They hear about the immigration issue on a daily basis, wherever they might go across the State of Iowa, New Hampshire, South Carolina, and beyond. The Presidential candidates are getting an earful from the American people. And the reason is, the American people understand that they are going to have to defend this central pillar of American exceptionalism called the rule of law. They rose up to defend it when, I call it, the comprehensive amnesty bill was brought before the Senate this year. We didn't bring a large bill before the House. I don't know if we are actually going to bring one. But twice it was brought before the Senate, and each time the American people rose up and they sent e-mails and they sent faxes and they made phone calls and they stopped in and visited their Senators in their district offices back in their States and also came out here to Washington to go into the Senate offices on the other side of the Capitol dome.

The presence of the American people, the intensity of the message that they delivered to our Senators said, we don't want amnesty. And however you define amnesty, the American people know what it is. And so what I have done is, Mr. Speaker, is I have brought the definition of ''amnesty'' to the floor of the House of Representatives so we can be talking about the same thing, because what I hear from the American people is the same thing that I believe, and I believe this:

The rule of law is sacrosanct and must be protected. We can't suspend the rule of law because it creates an inconvenience for an individual or a family or a class of people.

It is kind of like the Constitution itself in a way. The Constitution defines and protects our rights, and it is a unique document and it is the oldest document of its kind in the world. The oldest continuously functioning, surviving, effective Constitution in the world is ours, ratified in 1789. And that Constitution sets out parameters, guarantees individual rights, establishes the rule of law, determines where those laws are actually passed, here in this Congress or those responsibilities that are left to the States or to the people.

□ 1830

And yet when we disagree with the results of a constitutional decision, if the American people decide that we like our Constitution, we revere our Constitution and the parameters that are established in this Constitution, Mr. Speaker, if we want to change it, there are provisions in this Constitution to amend it.

We respect this Constitution as being sacrosanct; that it means what it says, and it means what the text of the Constitution said as understood at the time of ratification. And when we amend this Constitution, it's a pretty high bar, but the provision is in here because we are going to hold that standard and adhere to the language that's here because we understand that that's what holds this civilization and this society together. And if we want to amend it, then we go through the process of amending, and it has been done a number of times. It's a high bar.

But that standard of respect for that profound rule of the Constitution is the same standard that we need to have with respect for the profound viability of the rule of law. When we ignore laws, they're undermined. If we ignored the Constitution, if we simply decided I

don't like the results of the language that's here, I'm going to disregard this Constitution and cast it asunder and operate in a fashion that we see fit, if we do that, the Constitution is systemically destroyed. It would be destroyed by our failure to respect it. It would be destroyed by a Supreme Court that didn't respect the text of the Constitution. It actually has been undermined, in my opinion, by a number of the decisions of the Supreme Court when they didn't respect the text of the Constitution, its original intent and its original understanding.

And if the administration, the Department of Justice, if the people in this Congress, if the people in America don't have respect for the rule of law in the same fashion we must have respect for the Constitution itself, then the disrespect for the rule of law, the ignoring of the law, the failure to enforce the law, the turning a blind eye, the whisper, that's okay, the people that break the law because it's inconvenient to them, all of you, Mr. Speaker, all Americans who ignore the rule of law undermine it, erode it and erode that central pillar of American exceptionalism, the rule of law.

Think of this as a huge pillar that's been established by our founders. Think of building a large office building or a shining city on a hill or a castle. What would you put it on? You'd put it on a foundation. You would drill down to bedrock and you would build your foundation for a shining city on the hill or a castle or a large office building. You would build that foundation down to bedrock. And if you had to hold it together with a central pillar, build it all on the strength of one pillar, it would be a large pillar drilled to bedrock, and that pillar would be the rule of law.

There are other pillars, too, that you'd use to hold up the corners. Our Christian faith, the Judeo-Christian values, our family values, marriage, free enterprise, free enterprise capitalism, property rights, those things all are corner pillars that hold up the outside.

But the central pillar is the rule of law. And the things that we do in this country that disrespect that central pillar of American exceptionalism, the rule of law, erode it like it would erode a concrete or a marble pillar of a bridge, for example.

And all of us that might chip away by disregarding the law, by disrespecting the law, by failing to enforce the law, by turning a blind eye, by allowing entire classes of people to ignore and defy the law, those things become a corrosive agent that erodes that central pillar of American exceptionalism, that rule of law.

That's why it's so important that we adhere to the law. And if we don't like the law, then we need to come, Mr. Speaker, to the floor of this House of Representatives, offer legislation, offer amendments to the legislation, perfect that legislation in a full debate process here, and amend the law. Not ignore it.

And now I'm hearing from the administration that to not pass comprehensive immigration reform, which I refer to as a comprehensive amnesty plan, brings about de facto amnesty, in fact, amnesty, amnesty in reality. That's the language that's coming out of our administration and has been for the last couple of months since the people last rose up and drove another stake in the heart of the comprehensive amnesty plan.

Well, to not pass comprehensive immigration reform does not mean that there has to be a de facto amnesty. First we need to define what amnesty is. I have put this poster out here and this poster defines amnesty.

We've had many debates with the American people on what amnesty actually is. Presidential candidate after presidential candidate, politician after politician, Senator after Senator, Congressman after Congressman will tell you, I'm opposed to amnesty. And they will say that because they know the American people are opposed to amnesty. And in some of their cases they have a strong conviction that they're opposed to amnesty, Mr. Speaker. But that's not in all cases.

But in most cases they want to avoid the criticism of being a proponent for amnesty. And so to do that they say, I'm opposed to amnesty. The thing that they don't do is define amnesty. If you can't get them to define amnesty, then you have a pretty good suspicion that maybe they're not really against amnesty in all of its shapes and forms.

And so I've put up here the definition, after a careful study, of amnesty itself. Amnesty, to grant amnesty, Mr. Speaker, is to pardon immigration lawbreakers and reward them with the objective of their crime.

Now, a pardon for immigration lawbreakers, and generally an amnesty is a pardon to a class of people, a group of people. Whereas the President might pardon an individual, he has powers to do that, and that happens. Often it happened at the end of Bill Clinton's second term when he pardoned a large number of people for a variety of reasons.

Well, this is a pardon for a class of people. To define that pardon a little bit, class of people, would be the immigration law-breakers. All those people that came to the United States, both illegally, and those who came here legally and overstayed their visas, found themselves unlawfully present in the United States, or misrepresented their status here in the United States, maybe as a lawful immigrant without the right to work in the United States but misrepresented themselves in order to work and earn money. For whatever reason, they have broken immigration law. If they allowed their visa to expire and stayed in the United States, they've broken immigration law. If they came into the United States illegally, if they came here with contraband, if they came here and misrepresented themselves, if they worked when they didn't have a permit to work, if they came on a student visa and took a job, if they came on a visitor's visa and took a job, they've broken immigration law. To give them amnesty is to pardon them, those people who broke our immigration law. And that's really enough for that amnesty definition, but I thought I'd be a little more generous because this defines then what the Senate tried to do, what the majority in this House of Representatives seems to be seeking to do, and that is, not only grant them a pardon, not only grant them amnesty, the people that have broken our immigration laws, but also reward them with the objective of their crime or crimes. Pardon immigration lawbreakers, reward them with the objective of their crimes.

Now, I define that that way because some will say, well, reward them with a job. Some came here for a job. All did not. And, in fact, of the 12 million that the government admits are here, about 7 million of them are working. About 5 million of them are not. So it's clear that 42 percent of them who come here, even for a job, are not working. And some are keeping house, some are not in the work force in one fashion or another.

But I want to point out, Mr. Speaker, that we don't get one worker per illegal immigrant, one who comes across that border just for a job. Seven out of 12 are working. Five out of 12 are not. Fifty-eight percent are working, 42 percent are not. That's how it breaks down out of those that come into the United States.

What was their objective? Some was to get a better job, coming here for a better life. Some came in here with illegal drugs on them with the willful intent to smuggle those drugs into the United States, take them to the next level of the distribution chain, sell them, pocket the money. Some came in here illegally, dropped off their contraband and went back to get another load. And that goes on and on and on. Every single day, Mr. Speaker, there are people coming into the United States illegally carrying illegal drugs to the tune of $65 billion a year in illegal drugs coming across our southern border. That's 90 percent of the illegal drugs, $65 billion worth. And I'll perhaps come back to that.

But I wanted to drive this point in, Mr. Speaker. What is amnesty? And when a presidential candidate takes a position and says, I'm opposed to amnesty, I believe, Mr. Speaker, that the public should ask them, do you agree with STEVE KING's definition of amnesty? If not, what is your definition of amnesty? Do you agree that amnesty is to pardon immigration law-breakers and reward them with the objective of their crime? Or do you have another definition that allows you to grant amnesty and say that it's not amnesty? For example, if you require them to leave the United States and go, touch back to their home country, or go to

their embassy and sign up and then go into the work force, wouldn't you consider that to be amnesty? Do you think that you're waived from the responsibility of declaring it amnesty if you ask someone to pay a fine?

That's the Flake/Gutierrez bill, the bill that we held a hearing on. It will be 2 weeks ago tomorrow, Mr. Speaker, a large hearing on the largest amnesty bill that this Congress has seriously considered. We had witness after witness come forward, and they wanted to testify that this wasn't amnesty in that bill. It wasn't amnesty because it was going to require them to pay a fine. And I think in that bill it's a $2,500 fine.

Well, the going rate for a coyote to bring someone into the United States, and the report that comes back to me is, I'm sure it works cheaper but someplace in that $1,500 to $2,500 category is in the main of the going rate to be illegally brought into the United States and pay a coyote to do so. So the fine they'd ask to pay is equivalent to the freight that you would pay a coyote to bring you in illegally. That's what they would sell citizenship for, a path to citizenship. Not guaranteed. I'll concede that point to the other side. But it's not guaranteed because if you commit a crime, if you get in trouble with the law, if you're not on good behavior, if you don't at least sit through some English classes, then they don't want to give you citizenship.

But those provisions that are written in there are not provisions that are a higher standard that we'd ask of someone who came into the United States legally, someone who came here with a visa, someone who acquired a legal green card, someone who, in that 5-year program, could find themselves taking the oath of citizenship.

Another one of the allegations that's made is, well, if you're against this comprehensive immigration reform, they don't dare call it amnesty, and they wouldn't call someone who is here illegally a criminal, or they would not call them an illegal immigrant or an illegal alien. All of those terms, however accurate they are, are anathema to the people who want to pass their comprehensive immigration reform, which is comprehensive amnesty.

No, Mr. Speaker, they won't use those terms. They say undocumented immigrant who simply is here looking for a better life. True for some of them, Mr. Speaker, but certainly not true for all of them.

So we face the systemic devolution of the rule of law here in the United States, the rule of law that's founded upon this Constitution, that's written in the U.S. Code, and something that is established there as a majority of the House of Representatives and a majority of the Senate, and then signed by the President of the United States, and then the American people shut down the switchboards in the United States Senate because they oppose amnesty.

The American people, Mr. Speaker, are with me on this definition of amnesty, to pardon immigration lawbreakers and reward them with the objective of their crime.

And so today, we're involved in a political dynamic, and the political dynamic is this, that the people over on the majority side of the aisle, for the most part, see a political leverage gain if they can grant amnesty to the 12 to 20 or more million people that are in these United States illegally.

The people on the other side of the aisle, some of them, see an economic advantage and maybe a political advantage working with those who have gained an economic advantage by hiring the cheap labor. And so they say, this economy will collapse if we don't have the cheap labor that comes from, they will say, immigration, immigration, immigration.

When I ask them to define the difference between legal and illegal immigration they have a little trouble there, too, Mr. Speaker, because they have constantly, for the last 2 to 3 and more years, sought to blur the distinctions between legal and illegal.

And they will say that those of us that want to secure our borders and reestablish the rule of law and end automatic citizenship for babies that happen to be born to illegal mothers on U.S. soil, they will accuse us of all being against legal immigration.

□ 1845

But truthfully, those who undermine the rule of law, those who are for the open borders have brought about this debate that has tried to blur the two together, and because they are blurred together, we can't get at the real subject matter of how to establish a good, sound legal immigration policy because of 12 to 20 million illegals in the country. It's kind of like when you apply for a college education and there are only so many desks available in the classrooms, only so many slots available. Let's just say 20 million slots for immigration are filled up by people that broke American law to get here. That's 20 million slots that we can't give out of this Congress to somebody that respects our law. And that is not just a policy of American immigration that should be set by Congress, and the Constitution defines immigration as a responsibility for Congress to set. It's not just that. And it's not just that the people of America are denied the opportunity to establish immigration policy, because they are. But it's that 12 to 20 million or more people who have elected to break American laws are now sitting in those desks, taking up those slots, filling up the available space that we might have to bring a legal immigration policy.

So this immigration policy is out of our control. It is out of control here on the floor of the United States Congress, Mr. Speaker. It is out of control in the United States Senate. It's not within the control of the President of the United States or administration. It's out of our control. It's out of the control, out of the hands of the people of America. They shut down amnesty in the Senate by shutting down the phones, but another reason it is out of control is because people from other countries have broken our laws and have come here and every one that did so took away a piece of our ability to set our own policy here on the floor of the United States Congress.

So I will submit, Mr. Speaker, that the people I know, the people that align themselves with me, those who will stand up and speak for border enforcement and the rule of law and shutting off illegal immigration coming into this country, are not opposed to immigration. I don't know anyone that is opposed to legal immigration, smart immigration, and one day I will put this up on a poster too, Mr. Speaker, but an immigration policy that is designed to enhance the economic, the social, and the cultural well-being of the United States of America. That's the policy that we have a responsibility to deliver to the American people. And we do not have a policy to a foreign country that reflects a responsibility to them to relieve the poverty, the pain, the suffering that goes on in other countries in the world. We can reach out with some of our compassion, but we simply do not have an obligation to absorb the poverty in the world. In fact, we don't have the ability to do that.

What we do know is that this lifeboat, America, this wonderful Nation that God has gifted us with the responsibility to do the best we can within the parameters of the Declaration, the Constitution, the rule of law and those pillars that I mentioned, all of those things, we have a responsibility to preserve and protect this American way of life.

Think of America as a huge lifeboat. This lifeboat has got to have a captain. It has got to have a course chartered. It has to be steered. There have to be people pulling on the oars. And there have to be people that are unfurling the sails and swabbing the decks and down in the engine room and making this entire lifeboat of ours function and function properly. And if we go sailing off on a zig-zag course or drift with the winds up onto the shoals, eventually we will have so many passengers aboard this lifeboat that we will sink the lifeboat. At some point we can't function. The engine room doesn't work. We can't chart our course any longer because the load of humanity has gotten so great, and the process of training them and bringing them on board with our crew has gotten so far behind that we can't get it up to speed.

How many can we bring into America and still function? How many can we bring into America and maintain this overall greater American culture that we are?

The thing that binds us all together, this common sense of history, common sense of struggle, common sense of destiny, a common language. The language that binds us all together that

happens to be the most powerful unifying force known throughout history, throughout all mankind, is a common language. We start breaking that apart, and we find out that there are something like 37.5 million immigrants here in the United States, the largest number ever to be here, and in the highest percentages they speak foreign languages in their households. The American culture is being undermined and diminished, Mr. Speaker, by the illegal immigration that comes in.

And the legal immigration that we have, it's our job to set the valve down on that to allow an appropriate amount of legal immigration so that those that arrive here can do a number of things. The most important is that they assimilate into this civilization, into this American culture. That means they have to adapt to this broader American culture. It doesn't mean that you have to give up all of the culture of the foreign country. Those things that come from those countries that we adapt into this society, we would want to pick and choose the ones that are good. All things that come from other cultures are not good. There is a reason why people leave the countries that they leave. There is a reason why they come here.

I would like to say, Mr. Speaker, that this America is not just a giant ATM. It's not just some big machine that anyone can sneak across the border and punch that ATM and get some cash to come spitting out of it. This country is more than a cash transaction. This country is more than cheap labor for big business. This country is more than opening up our borders so that you can gain a political margin that's here and advance this cause of socialism on the left side and advance the cause of capitalism on the right side.

If you give either side the destination of their argument, if you give unlimited political power to those folks on the liberal side of the aisle, Mr. Speaker, and if you give unlimited economic advantage to the employers of cheap labor on not just the right side of the aisle, but I am finding out more and more on both sides of the aisle even more equally, turn those two forces loose with this policy on immigration, then big business will say ''I want more cheap labor'' and big politics will say ''I want more political power.''

So they bring in 2 million, 5 million, 10 million, 20 million more and pour those into the equation, and business comes out with their cheap labor and left-wing politics comes out with their political power. But what happens to the middle, Mr. Speaker? What happens to the American people? What happens to blue-collar America? What happens to the union worker who has trained, has skills, and has organized his ability to be able to collectively bargain and sell his skills as a unit with his other union members? How difficult is it to sell your skills as a unit and collectively bargain when you're watching 11,000 people a night pour across our southern border that come in that are low skilled or unskilled? How difficult is it to market yourself as a labor unit, a blue-collar labor unit, into an economy that is bringing more people in that will work cheaper than you want to work? How difficult is it to strike a labor agreement in a factory when there are tens of thousands, in fact, maybe even tens of millions of people outside that factory that will take those jobs at a cut rate from what you are getting today? How do you negotiate for a raise if there are thousands of people sitting outside the gates of your plant and those thousands of people are saying, I know, you're making $22 an hour and you're having trouble making ends meet with taxes as high as they are and having to make your copayment on your health insurance and on your retirement plan?

I know that $22 an hour squeezes you down a little tight and you would like to get a raise, maybe 5 percent, 6 percent raise. You are willing to turn up a little more production, add a little more professionalism, to be able to work better with management to produce a product that is going to be more competitive. That is how things work between management and labor when it's working right. But what kind of leverage do you think you have, blue-collar America, when there are tens of thousands of people outside the gates of the factory that say, $22 an hour? I will work for $10 an hour. I will work for $9. I will work for $8. And if you give them their $10-an-hour job, they will go to work for that, of course, and they won't press for a raise. And if you bring in another 1 or 2 or 5 or 10 million people, that $10-an-hour job is being pressured by the people who want to work for $5 or $6 an hour.

You have to understand that labor is a commodity. It is a commodity like corn or beans or gold or oil. The value of labor is determined by supply and demand in the marketplace. Labor is a commodity. That's why labor unions throughout history have always wanted to see a tight labor market so that they can negotiate for a good return on the labor. And business can operate in that kind of environment, too, because they want a high level of professionalism. They want job safety. They want skilled employees, people that are proud of what they do, people that can come in as a unit. And that is the bargaining power that is there.

Now, I want to emphasize also that I support merit shop employees. You don't have to be organized to market your skills. If you have a skill and you bring that flexibility to the job and the employer looks at that and determines, here is someone that doesn't come out of a labor shop or a labor union but I can use him in four, five, or six different areas here and he is flexible enough that he can jump from machine to machine for me on the factory floor or out on the construction job. Someone that you want to make sure that you can provide health insurance for them as an employer and retirement benefits for them and vacation benefits for them. Those things all come because labor has value, and it is the hardest commodity to deal with if you're in business. The rest becomes fairly predictable, and that is what business wants also is predictability. But labor today, the blue-collar labor today, organized labor today, confounds my sense of rationale. And I would think that if you are a rank-and-file labor member that your rationale would be confounded too, because the people who do the negotiations for the unions in America should be pressing for a tight labor market and a higher wage and a higher benefit and better retirement plan and vacation time. That has got to be the push. And the trade-off is more skills, more training, more efficiency, more professionalism, let me say the symbiotic relationship between labor and management.

But what is happening is the leaderships within the union are going the other way. I think the union bosses have written off the rank-and-file union members. I think they have forgotten about the tight labor supply. I think they have decided that they will not have the political power here in America if they stake their future on smaller numbers of workers. So they must have made one of those calculuses back in the smoke-filled room that decided, let's just write off this group of people and let's bring in as many as we can. Let's go for an open borders policy. Let's adopt the people that are today illegal into our side of this argument, and if we can get them legalized, we can get them to vote and we will get political power, and eventually we will get what we want with higher wages and better benefits for our workers, which, by the way, translates into more power, more cash for union bosses.

Mr. Speaker, if we have blue-collar rank-and-file people out there, I do believe that they ought to take a very good look at the rationale behind the leadership within the unions that are filing a lawsuit against the Department of Homeland Security, because they are enforcing current immigration law, and they would go to court to get an injunction to stop just sending the no-match Social Security letters and asking them to take action to clean up the no-match Social Security numbers in America, whether or not there is a legal argument. And, Mr. Speaker, I don't believe there is a legal argument. I believe from the legal perspective it is a specious argument, but in any case, it is not a moral position that they have taken. It is not a moral position to say you shall not enforce the law and I'm going to go to the court with my ACLU and AFL–CIO lawyers and we're going to ball up this system and prove to you that we can shut down government enforcement of the laws. That, Mr. Speaker, is an active and willful assault on the central pillar of American exceptionalism called the rule of law.

□ 1900

That's taking a concrete stone and a concrete saw and cutting notches into that pillar of American exceptionalism, the rule of law, which eventually will topple the rule of law. Where do you get a job then, Mr. Speaker? Where does business do their business then? What is the future for the rest of the world if the American civilization capitulates to those kind of assaults? These are some of the things that are on my mind, Mr. Speaker, as I read the news and watch the things that are happening and engage in the debate in the Judiciary Committee, where we've had some hearings now on the massive amnesty plan called Flake-Gutierrez.

When I hear the constant statements being made that the U.S. economy would collapse if we didn't have the people that are doing the work in this country that are defined by them as ''undocumented,'' and those that I will call illegals, to address that subject matter, Mr. Speaker, first the American people need to understand that we are not hostage to any threat of running out of cheap labor in America. As I've read through history, I've yet to identify a single sovereign state throughout history that ever failed because of too low a supply, not enough cheap labor.

But in America today, you will see that the unemployment rates are the highest in the skills that are the lowest. That tells you that those jobs are being taken by people who have come across the border illegally or overstayed their visa, illegal aliens taking low-skilled jobs, many of them are illiterate in their own language and uneducated in their own language, and so they will take the lowest of skilled jobs because, whatever it is, it's better than where they came from. And unskilled Americans are missing out.

Now, we have something like a 13 percent high school dropout rate that would reflect my area, the region of the country that I'm in. The numbers go higher in different parts of the country. The numbers go up to 30 percent and more in inner cities. What's there for opportunities, Mr. Speaker, for those low-skilled Americans, American born or naturalized American citizens who are low skilled? What is there for them when the highest unemployment are in the lowest skilled jobs?

And so the question is, can we accept at face value the statement that an American economy can't function without the illegal labor that's here, without undocumented workers, to use their vernacular, Mr. Speaker? And I will argue that the American economy would function better if it had 100 percent legal workers that are here. Some immigrants, many naturalized, many naturally born American citizens, all of that put together, legal people in America working, are going to make this economy function better than opening up our borders for tens of millions of people who come in here without skills, without language, without the first indicators that they will be able to assimilate.

Here are some of the statistics that tell us why: We have 300 million people in America. That's a lot more than I thought we would have at this stage in my life. The administration won't answer the question of how many are too many; what do you think the population of America should be by the year 2050, or 2100 for that matter?

Three hundred million people in America, about 142 million people that are in the workforce. Now, if you look at that and you realize that those that are working in America, that are working unlawfully here, are about 6.9 million and, in fact, the testimony on the Flake-Gutierrez bill of the Judiciary Committee a couple of weeks ago, they said 7 million. So we're in there real close. We don't disagree. But let's just say my number, 6.9 million, I think they rounded their number up, 6.9 million working illegals in America. Well, that's a lot of folks. That's twice the population of the State of Iowa, for example. But as a percentage of the workforce, it amounts to about 4.7 percent of the overall workforce. And so 6.9 million people working, and that's out of their number of about 12 million altogether, and you can extrapolate that up to the 20 million or more that I think it is, but 6.9 million people working representing 4.7 percent of the workforce. But here's the catch, Mr. Speaker. They're doing 2.2 percent of the work. And they're working awfully hard to do that. I don't diminish the effort and the work ethic that's there. But we measure our gross domestic product by the overall production of the individuals that we have. Highly skilled, highly trained professional individuals command a high price, Mr. Speaker. The reason they do is because they're worth a lot, and they're worth a lot more. I have to pay a lawyer more than I get paid most of the time. We pay doctors more than we pay carpenters. We pay carpenters sometimes more than we pay taxi drivers. The list goes on because the value of the skills are also established in this society by supply and demand in the marketplace. That's the spectrum of the commodity that I defined as labor a little bit earlier, Mr. Speaker.

So 6.9 million illegals working out of the workforce here of 142 million, representing 4.7 percent of the workforce, producing 2.2 percent of the gross domestic product. Now, we're not going to pull the plug on that overnight. That's another one of those red herrings that get drug across the path of this debate. I don't know anyone who says we're going to go out here and in a single day round up 12 or 20 million people and put them on some transportation units and take them back where they came from. In fact, the Representative from Minnesota (Mr. ELLISON) in the Judiciary Committee asked this question of a witness, how many trains and boats and planes would it take to send them all back? I quite enjoyed the answer of the witness who said, Well, they got here somehow. They can get back somehow. They can take their own transportation and go back for the most part.

It's not the question of whether we're going to round everybody up and deport them. No one that is debating this policy is advocating that we actually do that. But let me just say, suppose, Mr. Speaker, suppose a magic wand were waved and the fairy dust came and sprinkled across all 50 States in America, and the sun went down, and tomorrow morning when it came up everyone who was here in this country illegally woke up in their home country magically, without angst, without trauma. Just suppose hypothetically everyone woke up tomorrow morning in a country that they were lawfully present, where they could lawfully work and lawfully contribute to the society and reform the countries that need it, we would be out, well, the 12 to 20 million people that are here today. The workforce, though, the point that is being argued, there would be 6.9 million jobs out there tomorrow morning at 8 o'clock, if everybody is going to clock in at the same time, 6.9 million jobs. Let's just say all those people worked on the same shift, 8 to 5, with an hour off for lunch, and they're all gone, and they represented 2.2 percent of your production and you had a factory that had a delivery deadline that said you're going to have to get your quota out that door and loaded on trucks and gone, and that day between 8 and 5, you've got to produce your daily quota. You get the notice at 7:30 in the morning that the fairy dust has been sprinkled and you're going to be missing 2.2 percent of your production that day. Well, as a CEO, that isn't a very tough question. If we're all a factory here, if I were the CEO, I would put out a memo, and it would take me about 5 minutes to figure out what to do, and that would be a memo that went out to everyone. When they punched in that day, there would be a little notice above the time clock: Punch in, you're coming to work at 8 o'clock, and your 15-minute coffee break, I'm sorry for this inconvenience, has to be ratcheted back to 9½ minutes this morning. It's got to be ratcheted back to 9½ minutes this afternoon because we've got 11 minutes of our 8-hour day here that will be lost in our production because 2.2 percent of the production didn't show up for work today. That's the magnitude on the American economy that we're dependent upon right now. The magnitude of 11 minutes out of an 8-hour day is the production that's being done by illegal work in America. Now, would anybody actually argue that we couldn't get by with 7 hours and 49 minutes of production instead of a full 8 hours of production?

There are a lot of other ways to solve the problem or skin the cat. You can shorten the lunch hour by 11 minutes. You could work 11 minutes past 5

o'clock. You could do any combination of those things. You could skip a coffee break and actually pick up production that day. It's not the equivalent even of one single coffee break on an 8-hour day if we did all of the American GDP in one-third of our 24 hours. But, of course, we know it's spread across all 24 hours and 24/7. That's the reality of it.

So 6.9 million people out of a workforce of 142 million, representing 4.7 percent of the workforce, doing 2.2 percent of work, representing 11 minutes out of an 8-hour day, and you could divide that by three if you wanted to spread it around. So it would be 3⅔ minutes, 3 minutes and 40 seconds out of each 8-hour shift, if you wanted to take it down that way, Mr. Speaker. Hardly something that this country can't adjust to or couldn't deal with, even if it were abrupt, let alone something that will only be incremental in its scope.

This is a red herring that has been drug across the path by the people on the other side. They have their reasons and their motivations, but a rational approach to an economic situation in America isn't something that they bring to the table, Mr. Speaker.

As a matter of fairness, I would also make the point that there are significant industries in this country that have become ever more dependent on illegal labor. That exists in the packing plant industry. It exists in the agriculture industry. It exists where there is a requirement for very low skills or trainable skills, and people that aren't required to have language skills often fit into that category as well.

But the lower skilled environments that have become more dependent upon illegal labor have done so incrementally. It's been an evolutionary process. In speaking, Mr. Speaker, to the organized blue collar workers in America, in some cases management has come in and broken the union and replaced the union with illegal labor, or let's say a mix of illegal labor. And as this flow began, the recruitment in foreign countries also opened up. While that was going on, the Federal Government was turning a blind eye to enforcement of immigration. And the people living in the communities didn't actually see it in its broader magnitude. And the resentment came a little bit at a time and the realization came a little bit at a time.

I have spoken at significant length here, Mr. Speaker, about the responsibility of what happens when foreign countries set our immigration policy, when illegal immigrants from foreign countries come in here and take a slot that a legal immigrant could have, that takes away our ability to set an immigration policy.

But the largest responsibility has been and the first blame has been on the administration's lack of enforcement. This takes us back to 1986, to that amnesty bill that at least President Reagan had enough frank intuition to declare it an amnesty bill. The distinctions between the 1986 bill and the legislation that's before this Congress today and the Senate this week are really not significant in their scope. Amnesty in '86 is amnesty today.

But when the '86 bill was passed, it was billed as an amnesty to end all amnesties, Mr. Speaker. And I, sitting out there in the countryside, running a construction company, struggling through the farm crisis, absorbed the statements that were made here on the floor of Congress by the leadership here in Congress, by the President of the United States when the '86 amnesty bill was passed. I knew that I had to collect I–9s from job applicants, and I had to take a good look at their driver's license and their other documentation and make sure that it was a credible representation of who they were. I did so diligently. Those I–9s are still in my files and they're covered with dust. Nobody ever came and checked on that. They probably didn't need to check a little construction company, but they needed to check some large companies. They needed to have a presence out there that they were enforcing immigration law. And from 1986, the great threat that the Federal Government would be out there aggressively enforcing that new immigration law that was an amnesty to end all amnesties was a huge threat, a cloud that hung over all of us. We wanted to make sure that we dotted the I's and crossed the T's. And we lived in fear that the Federal government would shut us down, fine us or imprison us for not following Federal law. That was 1986.

But every month that went by, the threat diminished because the enforcement didn't materialize to the extent that we anticipated at least. And every year that went by, the enforcement got less. And as we went through the Reagan years, it diminished. And as we went through the first Bush presidency, it diminished. And as it went through the Clinton presidency, I was full of frustration because I was honoring immigration law, and I was competing against my competitors who sometimes did not honor immigration law. And I had two choices: I could adhere to the law and hope for enforcement when that competition had cheaper labor because they violated the law. I could do that, or I could throw up my hands and say, Well, if he can do it, I can do it. Well, I was raised in a family that revered that central pillar of American exceptionalism, the rule of law, and respected it. I still revere it and respect it, even more so today, Mr. Speaker. So that option of ''if you can't lick 'em, join them'' wasn't an option for me because the rule of law and respect for it prevented me from going down that path.

□ 1915

Today, we have watched the enforcement decline incrementally. I went through the Reagan administration from 1986 until the completion of Ronald Reagan's term. George Bush, the first President Bush, his lack of enforcement diminished it. The Reagan years, by comparison, were pretty good. The first President Bush diminished from there.

When Bill Clinton came to office, I began to really watch closely the lack of enforcement in the Clinton administration. I was full of frustration, as a construction company owner, that I was competing against that lack of enforcement. Yet when I look back at the statistics of the companies that were sanctioned during the Clinton administration, I see that, on the graph, it continued its decline of enforcement through these years that we are in today with a little uptick in the last year. I am not yet convinced that that uptick in enforcement from this administration is an uptick that comes from conviction on the rule of law or whether it is an uptick in increase and enforcement of immigration law to send a message to us that there will be enforcement if you just give us the comprehensive amnesty plan that we have asked for. You can choose your opinion on that, Mr. Speaker. I choose not to come down on either side of that argument for the sake of this discussion here.

I will say that this country has not been well served over the last 20 years due to lack of enforcement of immigration law. The country has been flooded with people that came in here illegally because we haven't enforced our laws and part of the things that came with that. Now, I will make the point, and it is a point that the opponents would continually make. I will make the point that most who come here do break the law to come here. But their goal is to provide for their family. At some point you make that decision, however hard the decision is, to provide for your family. But all who come here are not coming here to provide for their family. All who come here are not coming here with the goal of getting a job and finding a better way and finding a path through legalization and then bringing the rest of their family members here. That all happens. I admire the family network. I admire the faith network. I admire the work ethic that is within a significant majority of those who come here both legally and illegally. But I have a charge. I have a responsibility. I took an oath to uphold the Constitution. The complication of that oath is that I uphold the rule of law, as well. So I look into the statistical data that tells us what happens when we don't enforce the rule of law.

I listened to the immigration hearings over the last 5 years of constant immigration hearings, not every week, but sometimes multiple times a week, averaging every week at least, Mr. Speaker. The testimony constantly came. We are losing 250, 300 and then on up to 450 and more people who died in the desert in an effort to come into the United States. That is sad. It is

tragic. I have seen the pictures. It is a hard thing to look at. But I began to think, Mr. Speaker, about that other responsibility, that responsibility that we all here in the Chamber have to the American people, the responsibility that is part of our oath to uphold the Constitution. The implication is we uphold also the rule of law.

So I began to ask the witnesses that were testifying as to the loss of life in the Arizona desert. But what has happened to the people that did make it into the United States? What has happened to the American citizens who fell victim to the hand of some of those who came in here that are criminals, recognizing that $65 billion worth of illegal drugs pours across our southern border every year? That is all a crime.

By the way, for the point of record, Mr. Speaker, anyone who alleges that it is not a crime to illegally enter the United States is wrong, that it is a criminal misdemeanor to cross the United States border in violation of U.S. law. So sneaking across the border in the middle of the night makes that person a criminal. One of the Presidential candidates said otherwise. He might be a district attorney or prosecuting attorney. Federal law says it is a criminal misdemeanor to enter the United States illegally. So those who do so, and among them are those who are smuggling in illegal drugs, among them are those who are trafficking in illegal humanity, among them are those who are trafficking in prostitution and victimizing small girls and children. In this huge human wave, we have contraband. We have criminals. They commit crimes here in the United States.

So, one of the questions is, what would happen to the drug distribution chain if the fairy dust were sprinkled across America and tomorrow morning everyone woke up legally? It would shut town the distribution of illegal drugs in America if magically tomorrow morning everyone woke up in a country that they were lawfully present in. It would shut it down literally, virtually, any way you want to describe it, Mr. Speaker, because the links in the chain of the distribution that start in places like Colombia, China, Mexico, 90 percent of the illegal drugs coming across our southern border, those links in the chain are links that are built within the stream of humanity which is the illegal humanity that is here in this country today. That is the path of their fellow travelers, however good their virtues are, however high their ideals of providing for their family, getting a job and creating a home, they still also provide a conduit within a culture that is the distribution of illegal drugs.

With those illegal drugs comes the massive damage to human potential, especially to our young people in America. Yes, we have a responsibility here to shut down that demand. That is ours. We need to take that on. I can't look the Mexican Government in the eye and say, ''You need to help us shut down the illegal drugs in America and that will solve the problem.'' It will not. We need to shut down the demand in America. That is an American problem. It is a problem that causes problems in Mexico as well. That is a different subject, Mr. Speaker, and I will take that up perhaps another time. But this conduit for illegal drugs is a conduit that flows within illegal populations in America, and there are links to every distribution chain in America that go through that illegal population. So, that is one thing that would happen.

Another thing that would happen is there is a high crime rate, a higher crime rate in all the donor countries that send us people across at least our southern border and probably all of our borders, a higher crime rate than we have here in America. For example, violent death in America, 4.28 per 100,000 people. That is a statistic. Mexico, 13.2 per 100,000. That is three times the violent death rate in Mexico to that of the United States. So one could presume that out of every 100,000 people you would bring in, you would have three times more murderers than you would have within a typical population of the United States. That is not, when you look at the broader scheme, Mr. Speaker, as surprising or shocking as when you realize that Mexico has a lower crime rate than most, I will say, all of its neighbors with the exception of the United States, and most of the countries that are south of Mexico have a higher crime rate.

For example, the violent death rate in Honduras is nine times that of the United States. El Salvador can't find any statistics on. I can tell you in Colombia the rate is 63 violent deaths per 100,000. It works out to be 15.4 times more violent deaths per 100,000 than there are in the United States. Out of there comes a lot of cocaine, drug network, and drug trafficking.

My point is, Mr. Speaker, that American people die at the hands of criminal aliens here in the United States at a rate that we can't quantify nor comprehend at this point. I have a responsibility to protect the American people. This immigration policy that we have here in America, Mr. Speaker, is not a policy to accommodate any country in the world. It is a policy designed to enhance the economic, social and cultural well-being of the United States of America.

Every immigration policy for every sovereign state in the world should be established with the interests of that sovereign state, whether it would be Mexico, the United States, Holland, Norway, Russia, you name it. Every sovereign state needs to set an immigration policy that strengthens them. I support that we first seal the border, build a fence, build a wall, shut off automatic citizenship to babies that are born here to illegal mothers, workplace enforcement, pass the New Idea Act, end Federal deductibility for wages and benefits that are paid to illegals, and shut down that jobs magnet. I support all of that. Force all traffic, both human, contraband and legal cargo through our ports of entry on our southern border. Beef them up. Add more science. Make sure that we are effective in the job that we do on our border. I support all of that. By doing so, we have shut down the jobs magnet and we have shut off the illegal traffic coming into the United States. We have really made it difficult to bring illegal drugs into the United States at the same time.

We do all of that, Mr. Speaker, and then what we get out of that other side is, now, we have cleared the field so we can establish a rational immigration policy for legal people, legal entrance into the United States, and we can score them according to their ability to contribute to this economy. We can put out a matrix, a point system, that says, especially if you are young you have a lot of time to contribute to the economy, if you have a high education, you are going to make a higher wage and you are going to pay more taxes and you are going to be able to fund your own retirement and that of a bunch of other people while you are here. We can score this system up so we can have an immigration policy that does enhance the economic, the social and the cultural well-being of the United States.

But what we cannot do, Mr. Speaker, is we can't grant amnesty. We can't pardon immigration lawbreakers. We can't reward them with the objective of their crimes. If we do that, we ultimately destroy the central pillar of American exceptionalism called the rule of law. If that happens, there is no foundation to build a greater America. There is no foundation upon which we can lift this country up to a greater destiny. There is only the devolution of a civilization that is great today, maybe was greater yesterday, and that would lose its opportunity to be greater tomorrow.

LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted to:

Mr. JOHNSON of Georgia (at the request of Mr. HOYER) for today.

Mr. KNOLLENBERG (at the request of Mr. BOEHNER) for today until 1:00 p.m. on account of personal reasons.

Mr. MCHUGH (at the request of Mr. BOEHNER) for today after 2:15 p.m. and for September 20 on account of personal reasons.

SPECIAL ORDERS GRANTED

By unanimous consent, permission to address the House, following the legislative program and any special orders heretofore entered, was granted to:

(The following Members (at the request of Mr. MCDERMOTT) to revise and extend their remarks and include extraneous material:)

Mr. CUMMINGS, for 5 minutes, today.
Mr. ETHERIDGE, for 5 minutes, today.
Mr. MCDERMOTT, for 5 minutes, today.
Mr. ROTHMAN, for 5 minutes, today.
Mr. INSLEE, for 5 minutes, today.
Ms. KAPTUR, for 5 minutes, today.
Ms. WOOLSEY, for 5 minutes, today.
(The following Members (at the request of Mr. SHIMKUS) to revise and extend their remarks and include extraneous material:)
Mr. POE, for 5 minutes, September 26.
Mr. JONES of North Carolina, for 5 minutes, September 26.
Mr. HULSHOF, for 5 minutes, September 20.
Mr. SHIMKUS, for 5 minutes, today.

SENATE BILLS REFERRED

A bill of the Senate of the following title was taken from the Speaker's table and, under the rule, referred as follows:

S. 558. An act to provide parity between health insurance coverage of mental health benefits and benefits for medical and surgical services; to the Committee on Energy and Commerce; in addition to the Committee on Education and Labor for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

BILLS PRESENTED TO THE PRESIDENT

Lorraine C. Miller, Clerk of the House reports that on September 19, 2007 she presented to the President of the United States, for his approval, the following bills.

H.R. 954. To designate the facility of the United States Postal Service located at 365 West 125th Street in New York, New York, as the ''Percy Sutton Post Office Building''.
H.R. 2669. To provide for reconciliation pursuant to section 601 of the concurrent resolution on the budget for fiscal year 2008.
H.R. 3218. To designate a portion of Interstate Route 395 located in Baltimore, Maryland, as ''Cal Ripken Way''.

ADJOURNMENT

Mr. KING of Iowa. Mr. Speaker, I move that the House do now adjourn.
The motion was agreed to; accordingly (at 7 o'clock and 26 minutes p.m.), the House adjourned until tomorrow, Thursday, September 20, 2007, at 10 a.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 8 of rule XII, executive communications were taken from the Speaker's table and referred as follows:

3334. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting an extension of the Department's Memorandum of Understanding Between the Government of the United States of America and the Government of the Republic of Peru Concerning the Imposition of Import Restrictions on Certain Categories of Archaeological Material from the Prehispanic Cultures and Certain Ethnological Material from the Colonial Period of Peru, pursuant to 19 U.S.C. 2602(g); to the Committee on Foreign Affairs.

3335. A letter from the Secretary, Department of the Treasury, transmitting the semiannual report detailing payments made to Cuba as a result of the provision of telecommunications services pursuant to Department of the Treasury specific licenses, as required by Section 1705(e)(6) of the Cuban Democracy Act of 1992, 22 U.S.C. 6004(e)(6), as amended by Section 102(g) of the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996, and pursuant to Executive Order 13313 of July 31, 2003, pursuant to 22 U.S.C. 6032; to the Committee on Foreign Affairs.

3336. A letter from the Assistant Legal Adviser for Treaty Affairs, Department of State, transmitting Copies of international agreements, other than treaties, entered into by the United States, pursuant to 1 U.S.C. 112b; to the Committee on Foreign Affairs.

3337. A letter from the Assistant Legal Adviser for Treaty Affairs, Department of State, transmitting Copies of international agreements, other than treaties, entered into by the United States, pursuant to 1 U.S.C. 112b; to the Committee on Foreign Affairs.

3338. A letter from the Assistant Legal Adviser for Treaty Affairs, Department of State, transmitting pursuant to the Taiwan Relations Act, agreements concluded by the American Institute in Taiwan on July 10, 2007, pursuant to 22 U.S.C. 3311; to the Committee on Foreign Affairs.

3339. A letter from the Deputy Director, Defense Security Cooperation Agency, transmitting pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, Transmittal No. 07-19, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Taipai Economic and Cultural Representative Office in the United States for defense articles and services; to the Committee on Foreign Affairs.

3340. A letter from the Deputy Director, Defense Security Cooperation Agency, transmitting pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, Transmittal No. 07-51, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Taipai Economic and Cultural Representative Office in the United States for defense articles and services; to the Committee on Foreign Affairs.

3341. A letter from the Secretary, Department of Defense, transmitting the report on Measuring Stability and Security in Iraq pursuant to Section 9010 of the Department of Defense Appropriations Act, 2006, Pub. L. 109-289; to the Committee on Foreign Affairs.

3342. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting a copy of Presidential Determination No. 2006-30, Waiving Prohibition on United States Military Assistance with Respect to Montenegro, pursuant to Public Law 107-206, section 2007(a); to the Committee on Foreign Affairs.

3343. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting a Memorandum of Justification under Sections 610 and 614 of the Foreign Assistance Act to provide energy assistance to the Democratic People's Republic of Korea; to the Committee on Foreign Affairs.

3344. A letter from the Secretary, Department of the Treasury, transmitting as required by section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c), and pursuant to Executive Order 13313 of July 31, 2003, a six-month periodic report on the national emergency blocking property of persons undermining democratic processes or institutions in Zimbabwe that was declared in Executive Order 13288 of March 6, 2003; to the Committee on Foreign Affairs.

3345. A letter from the Secretary, Department of the Treasury, transmitting as required by section 401(c) of the National Emergencies Act, 50 U.S.C. 1641(c), and section 204(c) of the International Emergency Economic Powers Act, 50 U.S.C. 1703(c), and pursuant to Executive Order 13313 of July 31, 2003, a six-month periodic report on the national emergency with respect to persons who commit, threaten to commit, or support terrorism that was declared in Executive Order 13224 of September 23, 2001; to the Committee on Foreign Affairs.

3346. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3347. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3348. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3349. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

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3353. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3354. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3355. A letter from the White House Liaison, Department of Justice, transmitting a report pursuant to the Federal Vacancies Reform Act of 1998; to the Committee on Oversight and Government Reform.

3356. A letter from the Secretary, Department of the Treasury, transmitting the strategic plan for fiscal years 2007 through 2012 in compliance with the Government Performance and Results Act of 1993 (GPRA); to the Committee on Oversight and Government Reform.

3357. A letter from the Assistant to the Director of Congressional Affairs, Federal Election Commission, transmitting the Commission's annual report for FY 2006 prepared in accordance with the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act), Pub. L. 107-174; to the Committee on Oversight and Government Reform.

3358. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; MD Helicopters, Inc., Model 369, YOH-6A, 369A, OH-6A, 369H, 369HM, 369HS, 369HE, 369D, 369E, 369F, and 369FF Helicopters [Docket No. FAA-2007-28449; Directorate Identifier 207-SW-18-AD; Amendment

39-15103; AD 2007-09-51] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3359. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB-145XR Airplanes [Docket No. FAA-2007-27981; Directorate Identifier 2007-NM-021-AD; Amendment 39-15107; AD 2007-13-03] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3360. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; McDonnell Douglas Model 717-200 Airplanes [Docket No. FAA-2007-27152; Directorate Identifier 2006-NM-219-AD; Amendment 39-15105; AD 2007-13-01] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3361. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Gulfstream Model GIV-X, GV, and GV-SP Series Airplanes [Docket No. FAA-2007-28373; Directorate Identifier 2007-NM-110-AD; Amendment 39-15104; AD 2007-12-25] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3362. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Boeing Model 747-400, 747-400D, and 747-400F Series Airplanes [Docket No. FAA-2006-23803; Directorate Identifier 2005-NM-238-AD; Amendment 39-15108; AD 2007-13-04] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3363. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; Airbus Model A330 and A340 Airplanes [Docket No. FAA-2007-27565; Directorate Identifier 2006-NM-215-AD; Amendment 39-15111; AD 2007-13-07] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

3364. A letter from the Program Analyst, Department of Transportation, transmitting the Department's final rule — Airworthiness Directives; BAE Systems (Operations) Limited Model BAe 146 and Avro 146-RJ Airplanes [Docket No. FAA-2007-27714; Directorate Identifier 2006-NM-277-AD; Amendment 39-15110; AD 2007-13-06] (RIN: 2120-AA64) received September 14, 2007, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. RANGEL: Committee on Ways and Means. H.R. 3539. A bill to amend the Internal Revenue Code of 1986 to extend financing for the Airport and Airway Trust Fund, and for other purposes; with an amendment (Rept. 110–334 Pt. 1). Ordered to be printed.

Mr. WELCH: Committee on Rules. House Resolution 664. Resolution providing for consideration of the bill (H.R. 2881) to amend title 49, United States Code, to authorize appropriations for the Federal Aviation Administration for fiscal years 2008 through 2011, to improve aviation safety and capacity, to provide stable funding for the national aviation system, and for other purposes (Rept. 110–335). Referred to the House Calendar.

Mr. OBERSTAR: Committee on Transportation and Infrastructure. H.R. 2095. A bill to amend title 49, United States Code, to prevent railroad fatalities, injuries, and hazardous materials releases, to authorize the Federal Railroad Safety Administration, and for other purposes; with an amendment (Rept. 110–336). Referred to the Committee of the Whole House on the State of the Union and ordered to be printed.

DISCHARGE OF COMMITTEE

Pursuant to clause 2 of rule XII, the Committee on Transportation and Infrastructure discharged from further consideration. H.R. 3539 referred to the Committee of the Whole House on the State of the Union, and ordered to be printed.

PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions were introduced and severally referred, as follows:

By Mr. TOM DAVIS of Virginia (for himself, Mr. WOLF, and Mr. MARCHANT):

H.R. 3579. A bill to amend title 5, United States Code, to facilitate the temporary reemployment of Federal annuitants, and for other purposes; to the Committee on Oversight and Government Reform.

By Mr. DINGELL (for himself, Mr. BARTON of Texas, and Mr. PALLONE):

H.R. 3580. A bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.; to the Committee on Energy and Commerce. considered and passed.

By Mr. JONES of North Carolina:

H.R. 3581. A bill to clarify the roles of the Department of Defense and Department of Veterans Affairs disability evaluation systems for retirement and compensation of members of the Armed Forces for disability, to require the development of a single physical exam that can be used to determine both fitness for duty and disability ratings, to standardize fitness testing among the Armed Forces, and for other purposes; to the Committee on Armed Services, and in addition to the Committee on Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Ms. WOOLSEY:

H.R. 3582. A bill to amend the Fair Labor Standards Act of 1938 to clarify the exemption for home health care workers from certain provisions of that Act; to the Committee on Education and Labor.

By Mr. HENSARLING (for himself, Mr. AKIN, Mrs. BACHMANN, Mr. BACHUS, Mr. BARRETT of South Carolina, Mr. BARTLETT of Maryland, Mr. BARTON of Texas, Mr. BISHOP of Utah, Mrs. BLACKBURN, Mr. BRADY of Texas, Mr. BROUN of Georgia, Mr. BURTON of Indiana, Mr. CAMPBELL of California, Mr. CONAWAY, Mr. COLE of Oklahoma, Mr. MARIO DIAZ-BALART of Florida, Ms. FALLIN, Mr. FEENEY, Mr. FLAKE, Mr. FORTUÑO, Ms. FOXX, Mr. FRANKS of Arizona, Mr. GARRETT of New Jersey, Mr. HOEKSTRA, Mr. KING of Iowa, Mr. LAMBORN, Mr. DANIEL E. LUNGREN of California, Mr. ISSA, Mr. MANZULLO, Mr. MCHENRY, Mr. MILLER of Florida, Mrs. MUSGRAVE, Mrs. MYRICK, Mr. PENCE, Mr. PITTS, Mr. PRICE of Georgia, Mr. ROSKAM, Mr. RYAN of Wisconsin, Mr. SESSIONS, Mr. SHADEGG, and Mr. WELDON of Florida):

H.R. 3583. A bill to prevent Government shutdowns; to the Committee on Appropriations.

By Mr. BARTON of Texas (for himself, Mr. DEAL of Georgia, Mr. BOEHNER, Mr. SHIMKUS, Mr. WALDEN of Oregon, Mr. SESSIONS, Mrs. MYRICK, Mr. ROHRABACHER, Mr. PUTNAM, Mr. PITTS, Mr. KINGSTON, Mr. MCCAUL of Texas, Mr. PORTER, Mr. LEWIS of Kentucky, Mr. HASTERT, Mr. WESTMORELAND, Mr. PICKERING, Mr. HASTINGS of Washington, Mr. BURGESS, Mr. BLUNT, Mr. HULSHOF, Mr. RADANOVICH, Mr. BAKER, Mr. BUYER, Mr. HALL of Texas, Mr. HAYES, Mr. BARTLETT of Maryland, Mrs. BLACKBURN, Mr. CAMP of Michigan, Mr. STEARNS, Mr. HOEKSTRA, Ms. GRANGER, Mr. MCCOTTER, Mr. PEARCE, Mr. LUCAS, Mr. MICA, Mr. LATOURETTE, Mr. SMITH of Nebraska, Mr. WELLER, Mr. TERRY, Mrs. DRAKE, Mr. ADERHOLT, Mr. PRICE of Georgia, Mr. SAM JOHNSON of Texas, Mr. ISSA, Mr. HELLER, Mr. SULLIVAN, Mr. ROSKAM, Mr. YOUNG of Alaska, Mr. THORNBERRY, Mr. MANZULLO, Mr. NEUGEBAUER, Mr. REYNOLDS, Mr. ROGERS of Alabama, Mr. NUNES, Mr. BARRETT of South Carolina, Mr. KUHL of New York, Mr. CONAWAY, Mr. SOUDER, Mr. BILBRAY, Mr. GINGREY, Mr. BROWN of South Carolina, Mr. SHUSTER, Mr. BOUSTANY, Mr. WHITFIELD, Mr. KIRK, Mr. LINDER, Mr. MILLER of Florida, Mr. MCCARTHY of California, Mr. SMITH of Texas, Mr. GOHMERT, Mr. CARTER, Mr. MARCHANT, Mr. ROGERS of Michigan, Mr. GALLEGLY, Mr. MCCRERY, Mr. GARY G. MILLER of California, Mr. WAMP, Mr. HERGER, Mr. DAVID DAVIS of Tennessee, Mr. CHABOT, Mr. BONNER, Mr. BOOZMAN, Mr. BILIRAKIS, Mr. CALVERT, Mr. WICKER, Mr. LINCOLN DIAZ-BALART of Florida, Mr. MARIO DIAZ-BALART of Florida, Mr. BUCHANAN, Mr. ALEXANDER, Mr. DREIER, Mrs. MCMORRIS RODGERS, Mr. POE, Mr. LATHAM, Mr. COBLE, Mr. CASTLE, Mr. DENT, Mr. PETERSON of Pennsylvania, Ms. ROS-LEHTINEN, Mr. RYAN of Wisconsin, Mr. MCKEON, Mrs. MILLER of Michigan, Mr. DAVIS of Kentucky, Mr. GILCHREST, Mr. GRAVES, Mr. TOM DAVIS of Virginia, Mr. ROGERS of Kentucky, Mr. TIBERI, Mr. HUNTER, Mr. KING of Iowa, Mr. BRADY of Texas, Mr. WALBERG, and Mr. JOHNSON of Illinois):

H.R. 3584. A bill to amend title XXI of the Social Security Act to extend funding for 18 months for the State Children's Health Insurance Program (SCHIP), and for other purposes; to the Committee on Energy and Commerce.

By Mr. BACA (for himself, Mr. KILDEE, Mr. KENNEDY, Mrs. NAPOLITANO, Mr. GRIJALVA, Mr. PASTOR, Mr. REYES, Mr. ORTIZ, Mr. CUELLAR, Mr. RODRIGUEZ, Mr. HINOJOSA, Mr. BECERRA, Ms. ROYBAL-ALLARD, Mr. SIRES, Mr. GUTIERREZ, Mr. GONZALEZ, Ms. SOLIS, Mr. RAHALL, Mr. SALAZAR, Mr. HONDA, Mr. FALEOMAVAEGA, Mr. HASTINGS of Florida, Ms. PELOSI, Mr.

CARDOZA, Mr. GEORGE MILLER of California, Mr. COSTA, Mr. SERRANO, Ms. VELÁZQUEZ, Ms. LORETTA SANCHEZ of California, Mr. FILNER, Mr. LAMPSON, Mr. PALLONE, Mr. MITCHELL, Ms. JACKSON-LEE of Texas, Mr. GENE GREEN of Texas, Ms. HERSETH SANDLIN, Mr. SHULER, Mr. CLYBURN, Mr. MORAN of Virginia, Ms. MCCOLLUM of Minnesota, Ms. LEE, Mr. KAGEN, Mr. YOUNG of Alaska, Mr. COHEN, and Mr. KIND):

H.R. 3585. A bill to honor of the achievements and contributions of Native Americans to the United States, and for other purposes; to the Committee on Education and Labor.

By Mr. DUNCAN (for himself, Mr. BOSWELL, and Mr. GRAVES):

H.R. 3586. A bill to amend the Internal Revenue Code of 1986 to allow a credit against income tax for the production of certain material produced from organic matter which is available on a renewable or recurring basis; to the Committee on Ways and Means.

By Mr. FATTAH (for himself, Ms. JACKSON-LEE of Texas, Mr. TOWNS, Mr. KENNEDY, Ms. SCHAKOWSKY, Mr. CUMMINGS, Mr. DAVIS of Illinois, Mr. KUCINICH, Mr. ELLISON, and Mr. GRIJALVA):

H.R. 3587. A bill to establish a program to assist homeowners experiencing unavoidable, temporary difficulty making payments on mortgages insured under the National Housing Act; to the Committee on Financial Services.

By Mr. KING of New York:

H.R. 3588. A bill to amend the Consumer Product Safety Act to provide the Consumer Product Safety Commission with greater authority to require recalls, mandatory routine product testing, and for other purposes; to the Committee on Energy and Commerce.

By Mr. KING of New York:

H.R. 3589. A bill to amend the Trade Act of 1974 to extend trade adjustment assistance to certain service workers; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3590. A bill to amend the Internal Revenue Code of 1986 to extend for one year relief from the alternative minimum tax on individuals; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3591. A bill to amend the Internal Revenue Code of 1986 to provide that the net capital gain of certain individuals shall not be subject to tax; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3592. A bill to amend the Internal Revenue Code of 1986 to make the election to deduct State and local sales taxes permanent law; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3593. A bill to amend the Internal Revenue Code of 1986 to make permanent law the credit for nonbusiness energy property, the credit for gas produced from biomass and for synthetic fuels produced from coal, and the credit for energy efficient appliances; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3594. A bill to amend the Internal Revenue Code of 1986 to make permanent law the penalty-free distributions from retirement plans to individuals called to active duty; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3595. A bill to amend the Internal Revenue Code of 1986 to make permanent law the deduction for certain expenses of elementary and secondary school teachers; to the Committee on Ways and Means.

By Mr. LAMPSON:

H.R. 3596. A bill to amend the Internal Revenue Code of 1986 to make permanent law the tax-free distributions from individual retirement plans for charitable purposes; to the Committee on Ways and Means.

By Mrs. MCCARTHY of New York (for herself and Mr. LATOURETTE):

H.R. 3597. A bill to amend the Higher Education Act of 1965 to create a capitation grant program to increase the number of nurses and graduate educated nurse faculty to meet the future need for qualified nurses, and for other purposes; to the Committee on Education and Labor.

By Ms. MCCOLLUM of Minnesota:

H.R. 3598. A bill to prohibit the cessation, degradation, or limitation of broadcasting activities by the Broadcasting Board of Governors; to the Committee on Foreign Affairs.

By Ms. MOORE of Wisconsin:

H.R. 3599. A bill to authorize the Secretary of Health and Human Services to make grants to improve access to dependable, affordable automobiles by low-income families; to the Committee on Ways and Means.

By Mr. PAUL:

H.R. 3600. A bill to enforce the guarantees of the first, fourteenth, and fifteenth amendments to the Constitution of the United States by prohibiting certain devices used to deny the right to participate in certain elections; to the Committee on House Administration.

By Mr. PAUL:

H.R. 3601. A bill to restore to taxpayers awareness of the true cost of government by eliminating the withholding of income taxes by employers and requiring individuals to pay income taxes in monthly installments, and for other purposes; to the Committee on Ways and Means.

By Mr. PAUL:

H.R. 3602. A bill to amend the Communications Act of 1934 with respect to retransmission consent and must-carry for cable operators and satellite carriers; to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SIMPSON:

H.R. 3603. A bill to authorize the exchange of certain land located in the State of Idaho, and for other purposes; to the Committee on Natural Resources.

By Mr. UDALL of New Mexico:

H.R. 3604. A bill to amend the Internal Revenue Code of 1986 to treat certain payments made to the European Union in lieu of income taxes to a member of the European Union as income taxes paid to a foreign country for purposes of the foreign tax credit; to the Committee on Ways and Means.

By Mr. WALZ of Minnesota (for himself, Mr. KIND, Mr. OBERSTAR, Mr. PATRICK MURPHY of Pennsylvania, Mrs. BOYDA of Kansas, Mr. HILL, and Ms. MCCOLLUM of Minnesota):

H.R. 3605. A bill to amend the Internal Revenue Code of 1986 to increase, extend, and make permanent the above-the-line deduction for certain expenses of elementary and secondary school teachers; to the Committee on Ways and Means.

By Ms. WOOLSEY (for herself, Mr. HARE, Mr. LOEBSACK, Mr. SARBANES, and Mr. JEFFERSON):

H.R. 3606. A bill to amend the Elementary and Secondary Education Act of 1965 to provide grants for core curriculum development; to the Committee on Education and Labor.

By Mr. KUHL of New York (for himself, Mr. BOREN, Mr. PICKERING, and Mrs. CAPPS):

H. Con. Res. 215. Concurrent resolution supporting the designation of a week as ''National Cardiopulmonary Resuscitation and Automated External Defibrillator Awareness Week''; to the Committee on Oversight and Government Reform.

By Mr. KLINE of Minnesota (for himself, Mr. WILSON of South Carolina, Mrs. MCMORRIS RODGERS, Mr. GINGREY, Mr. ROSKAM, Mr. BUCHANAN, Mr. CARTER, Mrs. MUSGRAVE, Mr. KELLER, Mr. HASTERT, Mr. GOODE, Mr. LAHOOD, Mr. SESSIONS, Mr. ALEXANDER, Mr. BROUN of Georgia, Mrs. DRAKE, Mrs. BACHMANN, Mr. PITTS, Mr. HENSARLING, Mr. FEENEY, Mr. BOUSTANY, Ms. GRANGER, Mr. THORNBERRY, Mr. WELDON of Florida, Mr. TIM MURPHY of Pennsylvania, Mr. LAMBORN, Mr. REHBERG, Mr. SHIMKUS, Mr. REICHERT, Mr. DAVID DAVIS of Tennessee, Mr. PORTER, Mr. SAXTON, Mr. AKIN, Mr. WALZ of Minnesota, Mr. GOHMERT, Mr. MAHONEY of Florida, Mr. SNYDER, Mr. SMITH of New Jersey, Mr. FORTENBERRY, Mr. PUTNAM, Mr. SMITH of Washington, Mr. KILDEE, Mr. BOSWELL, Mrs. BLACKBURN, Mr. JORDAN, Mr. BOREN, Mr. TERRY, Mr. WELLER, Mrs. MILLER of Michigan, Mr. ANDREWS, Mr. ORTIZ, Mr. GENE GREEN of Texas, Mr. PETERSON of Minnesota, Mrs. BOYDA of Kansas, Mr. MCKEON, Ms. MCCOLLUM of Minnesota, Mr. ISSA, and Mr. YOUNG of Alaska):

H. Res. 663. A resolution supporting the goals and ideals of Veterans of Foreign Wars Day; to the Committee on Oversight and Government Reform.

By Mr. TOM DAVIS of Virginia (for himself, Ms. LORETTA SANCHEZ of California, and Ms. ZOE LOFGREN of California):

H. Res. 665. A resolution endorsing reforms for freedom and democracy in Vietnam; to the Committee on Foreign Affairs.

By Mr. RODRIGUEZ:

H. Res. 666. A resolution recognizing and celebrating the 35th anniversary of Guadalupe Mountains National Park, and for other purposes; to the Committee on Natural Resources.

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions as follows:

H.R. 211: Mr. CARNEY.

H.R. 371: Ms. LINDA T. SÁNCHEZ of California and Mr. HASTINGS of Florida.

H.R. 526: Mr. FRANK of Massachusetts.

H.R. 618: Mr. BROUN of Georgia.

H.R. 654: Ms. ROYBAL-ALLARD.

H.R. 743: Mr. BOOZMAN, Mr. YARMUTH, Mr. BILBRAY, Mr. WELDON of Florida, and Mr. HALL of Texas.

H.R. 821: Mr. SARBANES.

H.R. 854: Mr. WYNN.

H.R. 900: Mr. CARTER and Mr. ROSKAM.

H.R. 970: Mr. BUTTERFIELD and Mr. ANDREWS.

H.R. 971: Mr. LUCAS.

H.R. 977: Ms. DEGETTE.

H.R. 989: Mrs. WILSON of New Mexico.

H.R. 1110: Mr. TANNER, Mr. ELLSWORTH, Mr. MARCHANT, and Mrs. BONO.

H.R. 1125: Mr. LAMBORN, Mr. BOREN, Mrs. LOWEY, Mr. SESTAK, Mr. MORAN of Kansas, Mr. RYAN of Ohio, Mr. PENCE, Mr. HULSHOF, Ms. ROYBAL-ALLARD, Mr. WEXLER, Mr. PRICE of Georgia, Ms. ROS-LEHTINEN, Mr. WELDON of Florida, Mr. AKIN, and Mrs. EMERSON.

H.R. 1127: Mr. ROSKAM.

H.R. 1142: Mr. CARNAHAN.

H.R. 1155: Mr. BOUCHER.

H.R. 1190: Mr. PLATTS, Mrs. WILSON of New Mexico, Mr. RAHALL, and Mr. SOUDER.

H.R. 1201: Mr. KLINE of Minnesota, Mr. AKIN, Mr. WELDON of Florida, Mr. PITTS, Mr. FORTUÑO, and Mr. BISHOP of Utah.

H.R. 1213: Mr. ALTMIRE.
H.R. 1222: Mr. WOLF.
H.R. 1236: Mr. HALL of New York, Mr. TANNER, and Mr. DAVID DAVIS of Tennessee.
H.R. 1244: Mrs. NAPOLITANO.
H.R. 1275: Mr. TOWNS, Mr. WYNN, Mr. MARKEY, Mr. GUTIERREZ, and Mr. BLUMENAUER.
H.R. 1322: Mr. HIGGINS.
H.R. 1363: Mr. LAMPSON and Mr. GONZALEZ.
H.R. 1390: Mr. JONES of North Carolina.
H.R. 1422: Mr. BERMAN and Mr. TIERNEY.
H.R. 1439: Mr. PETERSON of Pennsylvania.
H.R. 1464: Mr. BOUCHER, Mr. WAXMAN, Mr. CARNAHAN, and Mr. BERMAN.
H.R. 1537: Mr. JOHNSON of Georgia.
H.R. 1553: Mr. BARRETT of South Carolina and Mr. SHULER.
H.R. 1576: Mr. PAYNE, Mr. OLVER, and Mr. RYAN of Ohio.
H.R. 1590: Mr. CARDOZA.
H.R. 1621: Mr. HINOJOSA.
H.R. 1634: Mr. ALLEN, Mr. GONZALEZ, and Mr. ARCURI.
H.R. 1644: Mr. SESTAK, Mr. BERMAN, Mr. PASTOR, and Mr. POMEROY.
H.R. 1683: Mr. GENE GREEN of Texas.
H.R. 1738: Mr. ABERCROMBIE and Mr. CARNEY.
H.R. 1843: Mr. KLINE of Minnesota, Mr. PERLMUTTER, and Mr. HERGER.
H.R. 1927: Mr. ISRAEL.
H.R. 1940: Mr. HALL of Texas.
H.R. 1960: Mr. BOREN and Mr. GORDON.
H.R. 1983: Mr. WAMP.
H.R. 1992: Mr. MCGOVERN, Mr. RUPPERSBERGER, Mr. UDALL of New Mexico, and Ms. MCCOLLUM of Minnesota.
H.R. 2015: Mr. TOWNS, Mr. BRALEY of Iowa, Mrs. BOYDA of Kansas, and Mr. GUTIERREZ.
H.R. 2054: Mr. UDALL of New Mexico.
H.R. 2138: Mr. DONNELLY and Mr. FORBES.
H.R. 2164: Mr. PATRICK MURPHY of Pennsylvania.
H.R. 2184: Mr. KENNEDY.
H.R. 2188: Mr. LEWIS of Kentucky.
H.R. 2231: Mr. BOUCHER and Mr. COHEN.
H.R. 2265: Mr. MARKEY.
H.R. 2266: Mr. CARNAHAN.
H.R. 2327: Mr. LEVIN, Mr. MCDERMOTT, Mr. HASTINGS of Florida, and Ms. CARSON.
H.R. 2390: Mrs. GILLIBRAND.
H.R. 2421: Ms. VELÁZQUEZ.
H.R. 2443: Ms. WATERS.
H.R. 2477: Mr. BRADY of Pennsylvania.
H.R. 2508: Mr. WAMP.
H.R. 2510: Mr. MCCARTHY of California.
H.R. 2539: Mr. AL GREEN of Texas.
H.R. 2585: Mr. WAMP and Mr. DAVID DAVIS of Tennessee.
H.R. 2593: Mr. UDALL of New Mexico and Mrs. CAPPS.
H.R. 2708: Mr. BOUCHER.
H.R. 2726: Mr. ETHERIDGE.
H.R. 2779: Mr. HODES and Mr. SNYDER.
H.R. 2807: Mr. JORDAN.
H.R. 2814: Mr. WAMP.
H.R. 2818: Mr. BAIRD and Mr. MORAN of Kansas.
H.R. 2820: Ms. ZOE LOFGREN of California.
H.R. 2915: Mr. ELLISON.
H.R. 2933: Mr. ISRAEL.
H.R. 2934: Mr. BARRETT of South Carolina.
H.R. 2964: Mr. REICHERT, Mr. VAN HOLLEN, Mr. BRALEY of Iowa, and Mr. FRANK of Massachusetts.
H.R. 3021: Mr. YARMUTH, Ms. MOORE of Wisconsin, and Mr. HARE.
H.R. 3033: Mr. FILNER.
H.R. 3075: Mr. ROSS.
H.R. 3076: Mr. PAUL and Mr. ROSS.
H.R. 3081: Ms. SUTTON, Mr. DAVIS of Illinois, Mr. DEFAZIO, Mr. JACKSON of Illinois, Ms. KAPTUR, Ms. KILPATRICK, Mr. LEWIS of Georgia, Mr. PAYNE, Ms. SCHAKOWSKY, Ms. WATSON, Mr. HARE, Mr. COHEN, and Mr. BRALEY of Iowa.
H.R. 3083: Mr. WELCH of Vermont.
H.R. 3090: Mr. PETERSON of Pennsylvania, Mr. COBLE, and Mr. POE.
H.R. 3168: Mr. JEFFERSON, Ms. CLARKE, and Ms. CASTOR.
H.R. 3177: Mr. MCCOTTER.
H.R. 3198: Mrs. DAVIS of California.
H.R. 3204: Mr. MCDERMOTT.
H.R. 3219: Mr. ARCURI and Mr. INGLIS of South Carolina.
H.R. 3256: Mr. MCDERMOTT, Ms. CARSON, Mr. BRADY of Pennsylvania, and Mr. COURTNEY.
H.R. 3257: Mr. KAGEN.
H.R. 3282: Ms. ZOE LOFGREN of California.
H.R. 3298: Ms. SUTTON.
H.R. 3317: Mr. JEFFERSON, Mr. BRADY of Pennsylvania, and Mr. MEEK of Florida.
H.R. 3329: Mr. ELLISON.
H.R. 3355: Mr. LYNCH.
H.R. 3358: Mr. BRADY of Pennsylvania and Mr. ROHRABACHER.
H.R. 3380: Mr. GOHMERT and Mr. YOUNG of Alaska.
H.R. 3393: Mr. DOYLE, Mr. HARE, and Mr. ELLISON.
H.R. 3405: Mr. HINOJOSA.
H.R. 3418: Mr. HOEKSTRA.
H.R. 3419: Mr. PRICE of North Carolina and Mr. WAMP.
H.R. 3432: Mr. FALEOMAVAEGA, Mr. SHERMAN, Mr. DELAHUNT, Mr. BURTON of Indiana, Mr. WELCH of Vermont, Mr. BRADY of Pennsylvania, Ms. MOORE of Wisconsin, Mr. FILNER, Mr. JOHNSON of Georgia, Mr. BAIRD, Mr. BISHOP of Georgia, Mrs. CHRISTENSEN, Mr. CLAY, Mr. CLEAVER, Mr. CLYBURN, Mr. COHEN, Mr. DAVIS of Alabama, Mr. DAVIS of Illinois, Mr. ETHERIDGE, Mr. FARR, Mr. FATTAH, Mr. HOLT, Mr. LAMPSON, Mr. JACKSON of Illinois, Ms. EDDIE BERNICE JOHNSON of Texas, Mrs. JONES of Ohio, Mr. MCNULTY, Mr. MARSHALL, Ms. NORTON, Mr. PALLONE, Mr. PASCRELL, Mr. PASTOR, Mr. PRICE of North Carolina, Mr. ROTHMAN, Mr. SCOTT of Georgia, Mr. SIRES, Mr. THOMPSON of Mississippi, Mr. UDALL of Colorado, Ms. WATERS, Mr. WATT, and Mr. WU.
H.R. 3448: Mrs. CAPPS.
H.R. 3481: Mr. BISHOP of New York, Mr. ALTMIRE, and Mr. PAYNE.
H.R. 3494: Mr. BILIRAKIS, Mr. CRAMER, Mr. LINCOLN DAVIS of Tennessee, Mr. MCINTYRE, Mrs. MILLER of Michigan, Mr. TAYLOR, Mr. CONAWAY, Mr. DENT, Mr. GERLACH, Mr. GRAVES, Mr. KUHL of New York, Mr. YOUNG of Alaska, and Mr. RYAN of Wisconsin.
H.R. 3502: Mr. PETRI.
H.R. 3508: Mr. HENSARLING, Mr. GERLACH, and Mr. GINGREY.
H.R. 3529: Mr. SESTAK.
H.R. 3531: Mr. BARTLETT of Maryland and Mr. JONES of North Carolina.
H.R. 3533: Ms. ROS-LEHTINEN, Mr. MATHESON, Mrs. CAPPS, Mr. CROWLEY, Mr. MCNULTY, Mr. HALL of New York, Mrs. MALONEY of New York, Mr. MCGOVERN, Mr. HASTINGS of Florida, Mr. BISHOP of New York, Mr. TOWNS, Mr. MCNERNEY, Mrs. BONO, Mr. CONYERS, and Mr. HAYES.
H.R. 3544: Mr. GOODE.
H.R. 3558: Mr. PETERSON of Minnesota and Mr. LOBIONDO.
H.R. 3577: Mr. DAVIS of Alabama and Mr. BRADY of Pennsylvania.
H.J. Res. 3: Mr. HARE and Mr. GONZALEZ.
H.J. Res. 6: Mr. TANCREDO, Mr. JONES of North Carolina, and Mr. GINGREY.
H.J. Res. 12: Mr. BACHUS.
H.J. Res. 48: Mr. DOGGETT.
H. Con. Res. 40: Mr. EVERETT, Mr. POE, Mr. BROUN of Georgia, Mrs. MYRICK, and Mr. ISSA.
H. Con. Res. 83: Mrs. EMERSON.
H. Con. Res. 122: Mr. AL GREEN of Texas and Mr. SIRES.
H. Con. Res. 160: Mr. GILCHREST.
H. Con. Res. 176: Mr. MOLLOHAN.
H. Con. Res. 200: Mr. SOUDER and Ms. DELAURO.
H. Con. Res. 203: Ms. LINDA T. SÁNCHEZ of California, Mr. HASTINGS of Florida, Mr. PENCE, and Mr. MCCAUL of Texas.
H. Con. Res. 205: Ms. SUTTON, Ms. BERKLEY, Ms. CLARKE, Ms. MOORE of Wisconsin, Mr. BUTTERFIELD, Mrs. TAUSCHER, Ms. MCCOLLUM of Minnesota, Mr. BERRY, Mrs. BOYDA of Kansas, Mr. MOLLOHAN, Ms. WATSON, Ms. WOOLSEY, Mr. GUTIERREZ, Ms. RICHARDSON, Ms. HERSETH SANDLIN, Mr. CLEAVER, Mr. DELAHUNT, Ms. SCHWARTZ, Mr. JACKSON of Illinois, Ms. LEE, Ms. SHEA-PORTER, Ms. DELAURO, Mr. YARMUTH, Mrs. NAPOLITANO, Mrs. MALONEY of New York, Ms. ESHOO, Mr. KAGEN, Mr. COURTNEY, Mr. PAYNE, Ms. BEAN, Mr. FARR, Mr. CROWLEY, Ms. WASSERMAN SCHULTZ, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. HODES, Mr. ELLISON, Ms. ZOE LOFGREN of California, Ms. SLAUGHTER, Mr. WELCH of Vermont, Mr. SESTAK, Mr. MORAN of Virginia, Mr. BERMAN, Mr. LOEBSACK, Ms. CASTOR, and Mr. SNYDER.
H. Con. Res. 210: Mr. AL GREEN of Texas, Mr. CLAY, Mr. GRIJALVA, Ms. LINDA T. SÁNCHEZ of California, Mrs. DAVIS of California, Mr. SESTAK, Mr. LOEBSACK, Mr. HOLT, Ms. CLARKE, Mr. HARE, Mr. YARMUTH, Mr. ALTMIRE, Mr. BISHOP of New York, Ms. HIRONO, Ms. SHEA-PORTER, Mr. SCOTT of Virginia, Mr. HINOJOSA, Mr. JACKSON of Illinois, Mr. SARBANES, Ms. BERKLEY, Ms. LORETTA SANCHEZ of California, Ms. ROYBAL-ALLARD, Mr. RODRIGUEZ, Ms. BALDWIN, Mr. BARROW, Mrs. TAUSCHER, Mr. KENNEDY, Ms. MCCOLLUM of Minnesota, Ms. VELÁZQUEZ, Mr. TOWNS, Ms. KILPATRICK, Mr. OLVER, Ms. WASSERMAN SCHULTZ, Mrs. MALONEY of New York, Ms. CARSON, Mr. MOLLOHAN, Mr. CUMMINGS, Ms. LEE, Mr. FATTAH, Mr. CLEAVER, Mr. ELLISON, Mr. HASTINGS of Florida, Mr. LEWIS of Kentucky, Ms. RICHARDSON, Ms. MOORE of Wisconsin, Mr. BUTTERFIELD, Mr. THOMPSON of Mississippi, Ms. NORTON, Ms. WATSON, Mr. PAYNE, Mr. SCOTT of Georgia, Ms. WATERS, Ms. JACKSON-LEE of Texas, Mr. WATT, Mrs. JONES of Ohio, Mr. BISHOP of Georgia, Mr. ENGLISH of Pennsylvania, Ms. CORRINE BROWN of Florida, Mr. PAUL, Mr. MCDERMOTT, Mr. PASCRELL, Mr. LIPINSKI, Mr. GUTIERREZ, Ms. BEAN, Mr. MANZULLO, Mr. WELLER, and Mr. COHEN.
H. Res. 79: Mr. ALTMIRE.
H. Res. 111: Mr. SESTAK and Mr. MCINTYRE.
H. Res. 194: Mr. THOMPSON of California and Mrs. CAPPS.
H. Res. 213: Mrs. CAPPS, Mr. KUCINICH, Mr. MCGOVERN, Mr. TOWNS, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Mr. MORAN of Virginia, Mr. OLVER, Mr. CARNAHAN, Mr. MICHAUD, Mr. HONDA, Ms. KILPATRICK, Mr. BERMAN, and Mr. DELAHUNT.
H. Res. 282: Mr. ORTIZ.
H. Res. 529: Mr. BRALEY of Iowa, Mr. COHEN, Mr. BLUMENAUER, Mr. ARCURI, Mr. DICKS, Mr. HODES, Mr. GRIJALVA, Mr. ALTMIRE, Mr. CUMMINGS, Mr. WALZ of Minnesota, Mr. CROWLEY, Mr. FILNER, Ms. BORDALLO, Mr. HINCHEY, Mr. MCCOTTER, and Mr. HOLT.
H. Res. 548: Mr. ENGLISH of Pennsylvania, Mr. PRICE of North Carolina, Mr. LAMBORN, and Mr. PALLONE.
H. Res. 576: Mr. ELLSWORTH.
H. Res. 584: Mr. SESSIONS, Mr. LATOURETTE, Mrs. CUBIN, Mr. GORDON, Ms. BERKLEY, Mr. COBLE, Mr. KNOLLENBERG, Mr. TERRY, Mr. KILDEE, Mrs. MCMORRIS RODGERS, Mr. DELAHUNT, Mr. BOOZMAN, Mr. PETERSON of Minnesota, Mr. DONNELLY, Mr. WICKER, Mr. GALLEGLY, Mr. COOPER, Mrs. BONO, Mr. POMEROY, Mr. WILSON of South Carolina, Ms. MATSUI, Mr. SMITH of Nebraska, Mr. WU, Ms. FOXX, Mr. ROSS, Mr. CONAWAY, Mr. PAUL, Mr. SPRATT, Mr. PICKERING, Mrs. BLACKBURN, Mr. MATHESON, Mr. PENCE, Mr. BARRETT of South Carolina, Mr. LEWIS of Kentucky, Ms. HIRONO, Mr. PLATTS, and Mr. TIBERI.
H. Res. 590: Mr. CONAWAY, Mr. SPRATT, Ms. SLAUGHTER, and Mr. POMEROY.
H. Res. 605: Mr. BOUCHER.
H. Res. 610: Mr. MARIO DIAZ-BALART of Florida, Mr. PENCE, and Mr. GOODE.

H. Res. 616: Mr. DOGGETT and Mr. HASTINGS of Florida.

H. Res. 618: Ms. WOOLSEY.

H. Res. 635: Mr. ROTHMAN.

H. Res. 640: Mr. WELLER, Mr. SMITH of Washington, Mr. DAVIS of Kentucky, Mr. KIRK, Mr. LIPINSKI, Mr. JOHNSON of Illinois, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. CORRINE BROWN of Florida, Ms. SCHAKOWSKY, Mr. ROSKAM, and Mr. LOBIONDO.

H. Res. 644: Mr. HOEKSTRA, Mr. DAVIS of Kentucky, Mr. FEENEY, Mrs. DRAKE, Mr. KUHL of New York, Mr. HASTERT, Mr. YOUNG of Florida, Mr. MARSHALL, Mr. COLE of Oklahoma, Mr. WHITFIELD, Mr. LINCOLN DIAZ-BALART of Florida, and Mr. ENGLISH of Pennsylvania.

H. Res. 652: Mr. WELCH of Vermont, Mr. TAYLOR, Mr. CASTLE, and Mr. BARROW.

DELETIONS OF SPONSORS FROM PUBLIC BILLS AND RESOLUTIONS

Under clause 7 of rule XII, sponsors were deleted from public bills and resolutions as follows:

H.R. 1644: Mr. RYAN of Wisconsin.